

Wales Research Ethics Committee 1
Cardiff

Mailing address:
Health and Care Research Wales
Castlebridge 5
15-19 Cowbridge Road East
Cardiff, CF11 9AB

email: Wales.REC1@wales.nhs.uk
website: www.hra.nhs.uk

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.

11 September 2024

Professor Bashir Al-Hashimi
Vice President (Research & Innovation)
King's College London
Vice President & Vice Principal (Research), King's College London
Room 8.11, 8th Floor Melbourne House
44-46 Aldwych
London
WC2B 4LL

Dear Professor Al-Hashimi

| | |
|--------------------------|--|
| Study title: | The UK-Irish atopic eczema systemic therapy cohort (A*STAR) |
| REC reference: | 18/WA/0200 |
| Protocol number: | A*STAR |
| Amendment number: | SA-04 |
| Amendment date: | 08 August 2024 |
| 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_SA-04] | 1.6 | 08 August 2024 |
| Participant information sheet (PIS) [A-STAR Adult Biorepository PIS-ICF - V3.2 - 20.05.24 clean] | 3.2 | 20 May 2024 |
| Participant information sheet (PIS) [A-STAR Adult Biorepository PIS-ICF - V3.2 - 20.05.24 Tracked] | 3.2 | 20 May 2024 |
| Participant information sheet (PIS) [A-STAR Parents_Guardians Biorepository PIS-ICF - V3.2 08.05.24 clean] | 3.2 | 08 May 2024 |
| Participant information sheet (PIS) [A-STAR Parents_Guardians Biorepository PIS-ICF - V3.2 08.05.24 tracked] | 3.2 | 08 May 2024 |
| Research protocol or project proposal [A-STAR Protocol V4.1 12.03.24 TRACKED] | 4.1 | 12 March 2024 |
| Research protocol or project proposal [A-STAR Protocol V4.1 clean] | 4.1 | 12 March 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/>

IRAS Project ID - 237309:

Please quote this number on all correspondence

Yours sincerely



Chair

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

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

Wales REC 1

Attendance at Sub-Committee of the REC meeting on 11 September 2024

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> |
|-------------------|--|----------------|
| Dr Sarah Brown | Research Associate in Applied Psychology and Public Health; Pharmacist (community pharmacy) | Yes |
| Mrs Kathie Fisher | Retired Company Director, Kingfisher Music | Yes |

Also in attendance:

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