Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

Wales Research Ethics Committee 1
Castlebridge 4
15-19 Cowbridge Road East
Cardiff
CF11 9AB

Telephone: 02920 785738
E-mail: jagit.sidhu@wales.nhs.uk
Website : www.hra.nhs.uk

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

26 July 2018

Dr Carsten Flohr
Consultant Dermatologist
St John's Insitute of Dermatology
1st floor, C Staircase, South Wing
Westminster Bridge Road
London
SE1 7EH

Dear Dr Flohr

Study title:	**The UK-Irish atopic eczema systemic therapy cohort (A*STAR)**
REC reference:	**18/WA/0200**
Protocol number:	**A*STAR**
IRAS project ID:	**237309**

Thank you for responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair, Wales REC 1.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Website database development proposal]	1.0	01 May 2018
Covering letter on headed paper [Cover letter REC_ASTAR]		14 May 2018
Covering letter on headed paper [A STAR Cover letter]	2	04 July 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [KCL insurance]		18 July 2017
IRAS Application Form [IRAS_Form_14052018]		14 May 2018
IRAS Checklist XML [Checklist_26072018]		26 July 2018
Letter from funder [BSF funding letter]		13 July 2017
MHRA Notice of No Objection Letter (Medical Devices) and relevant correspondence [MHRA confirmation of non-CTIMP]		24 August 2017
Other [Answers to REC questions]	1	02 July 2018
Other [Answers to REC questions]		26 July 2018
Participant consent form [Patient withdraw form minor and carer]	1	23 April 2018
Participant consent form [Patient Withdraw form Adult]	1	23 April 2018
Participant information sheet (PIS) [Children & biorepository PIS AF]	1	16 February 2018
Participant information sheet (PIS) [Very young children PIS AF]	1	23 April 2018
Participant information sheet (PIS) [Very young children & birepository PIS AF]	1	23 April 2018
Participant information sheet (PIS) [Children PIS AF]	1	16 February 2018
Participant information sheet (PIS) [Adult PIS ICF tracked changes]	1.1	04 July 2018
Participant information sheet (PIS) [Adult PIS ICF final]	1.1	04 July 2018
Participant information sheet (PIS) [Adult Biorepository PIS ICF - TC]	1.1	04 July 2018
Participant information sheet (PIS) [Adult biorepository PIS ICF final]	1.1	04 July 2018
Participant information sheet (PIS) [Parent guardians PIS ICF tracked changes]	1.1	04 July 2018
Participant information sheet (PIS) [Parent guardian PIS ICF Final]	1.1	04 July 2018
Participant information sheet (PIS) [Parent guardian Biorepository PIS ICF tracked changes]	1.1	04 July 2018
Participant information sheet (PIS) [Parent guardians biorepository PIS ICF Final]	1.1	04 July 2018
Participant information sheet (PIS) [Young person PIS AF tracked changes]	1.1	04 July 2018
Participant information sheet (PIS) [Young person PIS ICF Final - AF]	1.1	04 July 2018
Participant information sheet (PIS) [Young person and biorepository PIS AF tracked changes]	1.1	04 July 2018

Document	*Version*	*Date*
Participant information sheet (PIS) [Young person & Biorepository PIS ICF Final - AF]	1.1	04 July 2018
Research protocol or project proposal [Protocol]	1	22 March 2018
Summary CV for Chief Investigator (CI) [Chief Investigator CV]		12 January 2016
Validated questionnaire [EQ-5D-5L adult]	1	
Validated questionnaire [EQ-5D-Y children]	1	
Validated questionnaire [POEM for self-completion]		
Validated questionnaire [POEM for proxy completion]		
Validated questionnaire [DLQI]		01 April 1992
Validated questionnaire [IDQOL]		01 January 2000
Validated questionnaire [CDLQI]		01 May 1993
Validated questionnaire [CDLQI cartoon]		
Validated questionnaire [Asthma control questionnaire]		01 July 2011

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.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

18/WA/0200	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

p.p.
Dr K J Craig
Chair

Email: jagit.sidhu@wales.nhs.uk

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Prof Reza Razavi - reza.razavi@kcl.ac.uk -*
Ms Jennifer Boston - Guy's & St Thomas' Foundation NHS Trust – R&D@gstt.nhs.uk
Serrano Sonia - Sonia.Serrano@gstt.nhs.uk