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Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

09 August 2018

Dear Dr Flohr

HRA and Health and Care Research Wales (HCRW) Approval Letter

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

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Prof. Reza Razavi
Tel: 0207 8483224
Email: reza.razavi@kcl.ac.uk

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **237309**. Please quote this on all correspondence.

Yours sincerely

Rekha Keshvara
Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Prof Reza Razavi*
Ms Jennifer Boston, Guy's & St Thomas' Foundation NHS Trust

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [Customised collaboration agreement]	draft	01 May 2018
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
HRA Statement of Activities [All sites]	2	10 July 2018
HRA Statement of Activities [PV sites]	2	10 July 2018
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 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
Participant information sheet (PIS) [Young person & Biorepository PIS ICF Final - AF]	1.1	04 July 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
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

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards?	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	Statement of Activities will act as agreement of an NHS organisation to participate.
4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	As per the Statement of Activities, a separate finance agreement will be used for sites.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments

Section	Assessment Criteria	Compliant with Standards?	Comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
There are two site-types; the 'all activity sites' will be part of the Biorepository, and will provide additional blood and skin samples at various time points. The pharmacovigilance (PV) sites will not collect additional blood and skin samples. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS or on the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net, or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

This confirms whether the sponsor's position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and Wales, and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Principal Investigator is expected to be in place at the participating NHS site. GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken.
Use of identifiable patient records held by an NHS organisation to identify potential participants should be undertaken by a member of the direct care team for the patient, so it would not normally be acceptable for this to be done by staff not employed by that organisation. An Honorary Research Contract (or equivalent) would be expected for any external NHS/research staff undertaking all of the other activities for the study once consent from the participant is in place. The pre-engagement checks should include an enhanced DBS check (including a check against the DBS 'barred list' for adults), and Occupational Health Clearance.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.