Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Andrew Poullis
Department of Gastroenterology
St George's Hospital
Tooting
SW17 0QT

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

31 March 2020

Dear Dr Poullis

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

Study title:	**Clinical associations with pancreatic exocrine insufficiency**
IRAS project ID:	**277277**
Protocol number:	**1.0**
REC reference:	**20/LO/0433**
Sponsor	**St George's University of 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.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

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 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) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

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 standard conditions 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.

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 **277277**. Please quote this on all correspondence.

Yours sincerely,

Rekha Keshvara

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Mrs Hayley Colleran-Saunders*

List of Documents

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

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [SGUL Insurance Document]	1.0	25 February 2020
IRAS Application Form [IRAS_Form_28022020]		28 February 2020
Research protocol or project proposal [Study protocol v1.0]	1.0	21 February 2020
Summary CV for Chief Investigator (CI) [CI summary CV]	1.0	25 February 2020
Summary CV for student [Student summary CV]	1	06 December 2019
Summary CV for supervisor (student research) [Supervisor CV]	1.0	25 February 2020

IRAS project ID	277277

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
There is one participating NHS organisation taking part in the study in England. Therefore, there is one site-type undertaking the research activities as detailed in the study protocol.	This is a single site study where the site and the sponsor have a joint Research office arrangement in place. You should work with your sponsor R&D office to make arrangements to set up the study. The sponsor R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.	This is a single site study where the site and the sponsor have a joint Research office arrangement in place and therefore, a study agreement is not expected for the trail.	No application for external funding has been made.	A Principal Investigator is expected to be in place at the participating NHS sites.	It is likely that all study activities will be undertaken by local staff employed by the NHS organisation. Therefore, HR good practice arrangements are not expected for the trial.

Other information to aid study set-up and delivery

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 do not intend to apply for inclusion on the NIHR CRN Portfolio.