Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

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Dear Dr Battersby

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

Study title:	**Management of Patent Ductus Arteriosus in babies admitted to UK neonatal units: a population-based study using the National Neonatal Research Database**
IRAS project ID:	**284040**
Protocol number:	**1.1**
REC reference:	**20/LO/0825**
Sponsor	**Imperial 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.

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 **284040**. Please quote this on all correspondence.

Yours sincerely,

Kevin Ahmed
Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Miss Ruth Nicholson*

List of Documents

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

Document	*Version*	*Date*
HRA Schedule of Events [HRA Schedule of Events]		26 May 2020
IRAS Application Form [IRAS_Form_18052020]		18 May 2020
Organisation Information Document [Organisation Information Document]		26 May 2020
Research protocol or project proposal [Protocol]	1	12 May 2020
Summary CV for Chief Investigator (CI) [CV CI]	1	12 May 2020
Summary CV for student [Summary CV for student - Derek Chan]		
Summary CV for supervisor (student research) [Summary CV for supervisor - Chris Gale]		11 September 2019

IRAS project ID	284040

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
This is a single site study. There is therefore one site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	No application for external funding will be made	A Principal Investigator should be in place at participating NHS organisations in England. The Chief Investigator will take on this role at the sole participating site.	It is unlikely that letters of access or honorary research contracts will be applicable, except where external staff employed by another Trust (or University) are involved (and then it is likely that arrangements are already in place). Where arrangements are not already in place, external staff would be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

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.