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Email: hra.approval@nhs.net
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15 May 2019

Dear Dr Dassios

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

Study title:	**Nutrition and respiratory morbidity in extremely premature infants: a retrospective five-year whole population study of neonatal networks in England.**
IRAS project ID:	**259225**
Protocol number:	**N/A**
REC reference:	**19/WM/0172**
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.

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 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 **259225**. Please quote this on all correspondence.

Yours sincerely,

Chris Kitchen

Email: hra.approval@nhs.net

Copy to: *Professor Reza Rezavi*

List of Documents

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

Document	*Version*	*Date*
IRAS Application Form [IRAS_Form_26042019]		26 April 2019
Letter from sponsor [Indemnity/Insurance]	1	09 July 2018
Other [Validation query]		08 May 2019
Research protocol or project proposal [Protocol]	v1.0	15 January 2019
Summary CV for Chief Investigator (CI) [CI summary CV]	1	01 January 2019
Summary CV for student [Student CV]	1	30 November 2018

IRAS project ID	259225

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 non-commercial study with a single participating NHS organisation, where that organisation is also the study co-sponsor.	This is a single site study co-sponsored by the participating NHS organisation. 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 non-commercial single site study taking place in the NHS where that single NHS organisation is also the study co-sponsor. Therefore no study agreements are expected.	No application for external funding has been made.	A Principal Investigator is expected to be in place at the participating organisation.	For research team members that do not have existing contractual relationships with the participating organisation, Letters of Access should be in place if the activities undertaken at the NHS site involve access to anonymised patient data on-site, on the basis of Research Passports (if University employed) or NHS to NHS confirmation of pre-engagement checks letters (if NHS employed). The pre-engagement checks are not expected to include DBS checks or Occupational Health Clearance.

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 will not make an application to the CRN Portfolio.