Professor Neena Modi
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03 December 2019

Dear Professor Modi

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

Study title:	**DEEPNEO: A machine-learning approach to describe variations in clinical practice and patient outcomes in neonatal units in England and Wales**
IRAS project ID:	**273001**
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 *"After HRA Approval – guidance for sponsors and investigators"* document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, 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 **273001**. Please quote this on all correspondence.

Yours Sincerely

Beverley Mashegede

Email: hra.approval@nhs.net

Copy to: Ms Becky Ward, Sponsor Contact

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_19112019]		19 November 2019
IRAS Application Form XML file [IRAS_Form_19112019]		19 November 2019
IRAS Checklist XML [Checklist_19112019]		19 November 2019
Letter from funder [BRC Award letter]		17 September 2018
Letter from sponsor [Insurance Approval]		30 October 2019
Organisation Information Document [OID Document Data Processing]	Version 1	07 November 2019
Research protocol or project proposal [DEEPNEO Protocol Version 1]	Version 1	29 September 2019
Summary CV for Chief Investigator (CI) [Modi CV]		30 October 2019

IRAS project ID	273001

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
Single centre study.	This is a single site study where the Sponsor and the participating NHS organisation have joint research offices. You should work with your R&D office to make arrangements to set up the study. The joint R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.	An Organisation Information Document (Data Processing Agreement ONLY) has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	Funded by NIHR Biomedical Research Centre.	A PI is expected at the participating organisation.	All study activities will be undertaken by local staff employed by the NHS organisation. Therefore, no honorary research contracts or letters of access are expected for this study.

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 <u>do not</u> intend to apply for inclusion on the NIHR CRN Portfolio.