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29 October 2025

Dear Prof Modi

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

Study title:	An efficient, UK-wide, real-world-data-enabled, adaptive, 2-randomisation, controlled trial to determine clinical efficacy, effect size, and safety of widely used enteral feeds in reducing necrotising enterocolitis, mortality, and cognitive impairment in preterm babies born below 29 weeks gestation
IRAS project ID:	337660
Protocol number:	181495
REC reference:	25/LO/0697
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

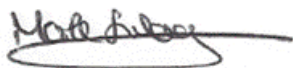
The [HRA website](#) also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

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 **337660**. Please quote this on all correspondence.

Yours sincerely,



Mark Sidaway

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Ms Ruth Nicholson*

List of Documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Contract/Study Agreement template [COLLABORATE mNCA]		
Copies of materials calling attention of potential participants to the research [COLLABORATE Animation Text]	2.0	22 October 2025
Copies of materials calling attention of potential participants to the research [COLLABORATE Randomisation Animation Text]	2.0	22 October 2025
Copies of materials calling attention of potential participants to the research [COLLABORATE Animation Text]	2.0	22 October 2025
Copies of materials calling attention of potential participants to the research [COLLABORATE Randomisation Animation Text]	2.0	22 October 2025
Copies of materials calling attention of potential participants to the research [COLLABORATE Animation Flyer 2 (pink)]	1.3	04 April 2025
Copies of materials calling attention of potential participants to the research [COLLABORATE Animation Flyer 2 (yellow)]	1.3	04 April 2025
Copies of materials calling attention of potential participants to the research [COLLABORATE Flyer 1 (pink)]	2.3	04 April 2025
Copies of materials calling attention of potential participants to the research [COLLABORATE Flyer 2 (yellow)]	2.3	04 April 2025
Covering letter on headed paper [COLLABORATE REC Cover Letter]		22 August 2025
Covering letter on headed paper [COLLABORATE REC Cover Letter]		22 October 2025
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Imperial Insurance Certificate]		04 August 2025
GP/consultant information sheets or letters [COLLABORATE Sub-Study GP Letter]	1.0	15 August 2025
IRAS Application Form [IRAS_Form_26082025]		26 August 2025
Letter from funder [COLLABORATE Funder Letter]		08 January 2025
Letter from sponsor [COLLABORATE Sponsorship Letter]		21 August 2025
Letters of invitation to participant [COLLABORATE Verbal Consent Statement]	2.0	22 October 2025
Organisation Information Document [COLLABORATE OID]		
Other [COLLABORATE Protocol]	2.0	22 October 2025
Other [fetalneonatal-2017-July-102-4-F291-inline-supplementary-material-16 HRA response to UK REC]		
Other [fetalneonatal-2017-July-102-4-F291-inline-supplementary-material-16 Report to HRA]		
Other [Gale, Hyde, Modi ADC FN 2015]		
Other [COLLABORATE Paper Notes Randomisation 1_Formula]	1.0	15 August 2025
Other [COLLABORATE Paper Notes Randomisation 1_pHDM]	1.0	15 August 2025
Other [COLLABORATE Paper Notes Randomisation 2_Fortifier]	1.0	15 August 2025
Other [COLLABORATE Paper Notes Randomisation 2_Treatment as Usual]	1.0	15 August 2025
Other [COLLABORATE Website Text]	1.3	01 January 2025
Other [COLLABORATE Cot Card Pending Randomisation 1]	1.0	15 August 2025
Other [COLLABORATE Cot Card Pending Randomisation 2]	1.0	15 August 2025
Other [COLLABORATE Cot Card_Formula]	1.0	15 August 2025

Other [COLLABORATE Cot Card_pHDM]	1.0	15 August 2025
Other [COLLABORATE Cot Card_Fortification]	1.0	15 August 2025
Other [COLLABORATE Cot Card_Treatment as Usual]	1.0	15 August 2025
Other [COLLABORATE Paper Notes Consent Randomisation 2]	1.0	15 August 2025
Other [COLLABORATE Paper Notes Consent Randomisation 1]	1.0	15 August 2025
Participant consent form [COLLABORATE Verbal Consent Statement]	2.0	22 October 2025
Participant consent form [COLLABORATE Sub-Study ICF]	1.0	15 August 2025
Participant information sheet (PIS) [COLLABORATE PIS Part 1]	2.0	22 October 2025
Participant information sheet (PIS) [COLLABORATE PIS Part 1]	2.0	22 October 2025
Participant information sheet (PIS) [COLLABORATE PIS Part 2]	2.0	22 October 2025
Participant information sheet (PIS) [COLLABORATE PIS Part 2]	2.0	22 October 2025
Participant information sheet (PIS) [COLLABORATE PIS Part 1]	1.0	15 August 2025
Participant information sheet (PIS) [COLLABORATE Sub-Study PIS]	1.0	15 August 2025
Research protocol or project proposal [COLLABORATE Protocol]	2.0	22 October 2025
Summary CV for Chief Investigator (CI) [N Modi CV]		03 February 2025
Summary CV for Chief Investigator (CI) [Modi Neena 2 page CV]	N/A	01 August 2025
Validated questionnaire [PARCA-R Questionnaire]		

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
Research activities and procedures as per the protocol and other study documents will take place at participating NHS organisations.	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 in accordance with the contracting expectations detailed.	An Organisation Information Document has been submitted but the sponsor is intending to use a separate agreement. The sponsor has supplied the unmodified model agreement and intends to use this with participating NHS organisations.	Study funding arrangements are detailed in the Organisation Information Document	A Principal Investigator should be appointed at participating NHS organisations.	Where an external individual who does not already hold an NHS employment contract will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold an Honorary Research Contract. External staff holding pre-existing NHS employment contracts should obtain a Letter of Access. These should confirm Occupational Health Clearance. These should confirm enhanced DBS checks and appropriate barred list checks.

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 intend to apply for inclusion on the NIHR CRN Portfolio.