



Health Research Authority

London - Bloomsbury Research Ethics Committee

Health Research Authority
2 Redman Place
Stratford
London
E20 1JQ

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

08 October 2025

Prof Neena Modi
Professor of Neonatal Medicine, Consultant in Neonatal Medicine
Imperial College London
Section of Neonatal Medicine, Chelsea and Westminster Hospital campus,
School of Public Health, 369 Fulham Road
London
SW10 9NH

Dear Prof Modi

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
REC reference:	25/LO/0697
Protocol number:	181495
IRAS project ID:	337660

The Research Ethics Committee (REC) reviewed the above application at the meeting held on 01 October 2025. Thank you for attending to discuss the application.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Good practice principles and responsibilities

The [UK Policy Framework for Health and Social Care Research](#) sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of [research transparency](#):

1. [registering research studies](#)
2. [reporting results](#)
3. [informing participants](#)
4. [sharing study data and tissue](#)

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Number	Condition	Response from the applicant
1.	Please make the following changes in the PIS documents, ensuring they are tracked, and the date and version number are amended: a) Randomisation should not be framed as a benefit of taking part in the study. Although it does mean that participants will be fairly allocated to each feed, this cannot be portrayed as a benefit, especially considering that some of the babies will have been allocated to a feed that may be proven sub-optimal, as a result of the study. Although the study includes different feed options, allocation to each feed option is random so any wording to suggest that randomisation offers a benefit as it offers “choice”, should be removed or revised and a lay explanation of what randomisation means should be added. Please remove or revise any applicable wording, e.g., <i>“Your baby will benefit because the choice of which option they receive will be made fairly and equally.”</i>. b) Please remove any wording to suggest that inclusion in the study will provide benefit as the baby will be more closely monitored. Preterm babies in NICU are already very closely monitored and to imply that they will be better monitored if they are included in the study could be seen as coercive, especially for parents who are already likely to be very anxious about their baby’s care. E.g. <i>“Participants in randomised studies like COLLABORATE also often benefit because they receive care across a closely monitored pathway.”</i>.	
2	Please make the following changes to video/ animation text documents, ensuring the changes are tracked and the date and version number are amended:	

	a) The video explaining randomisation includes the wording, “<i>fair equal choice</i>” and “<i>best choice</i>”. As per action 1a above, randomisation is fair but should not be framed as beneficial or offering choice, please remove or revise the wording throughout. b) Similar changes should be made to the video explaining the study, the wording “fair and equal chance of getting the best choice.”, implies benefit from randomisation and is also rather laborious. Randomisation is fair/ equitable but should not be presented as beneficial. c) In the video text explaining the study, in the doctor’s second paragraph, please replace “worry” with “wonder if”. The word “worry” could be triggering for some parents.	
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You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a public registry before the first participant is recruited and no later than six weeks after. For this purpose, ‘clinical trials’ are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device

- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

A 'public registry' means any registry on the WHO list of primary registries or the ICMJE list of registries provided the registry facilitates public access to information about the UK trial.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: [Research registration and research project identifiers](#)).

Where a deferral is agreed we expect the sponsor to publish a [minimal record](#) on a publicly accessible registry. When the deferral period ends, the sponsor should publish the full record on the same registry, to fulfil the condition of the REC favourable opinion.

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Where the study is registered on ClinicalTrials.gov, please inform deferrals@hra.nhs.uk and the Research Ethics Committee (REC) which issued the final ethical opinion so that our records can be updated.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Where a deferral is agreed, [a minimum research summary](#) will still be published in [the research summaries database](#). At the end of the deferral period, we will publish the [full research summary](#).

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: [Research summaries - Health Research Authority \(hra.nhs.uk\)](#)

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming no objection or giving grounds for objection, as soon as this is available.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

- Reporting results

The latest guidance on these topics can be found at <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/>.

Ethical review of research sites

NHS/HSC Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
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
Copies of materials calling attention of potential participants to the research [COLLABORATE Animation Text]	1.3	04 April 2025
Copies of materials calling attention of potential participants to the research [COLLABORATE NNRD Animation Text]	1.2	04 April 2025
Copies of materials calling attention of potential participants to the research [COLLABORATE Randomisation Animation Text]	1.3	29 April 2025
Covering letter on headed paper [COLLABORATE REC Cover Letter]		22 August 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
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
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
Participant consent form [COLLABORATE Sub-Study ICF]	1.0	15 August 2025
Participant consent form [COLLABORATE Verbal Consent Statement]	1.0	15 August 2025
Participant information sheet (PIS) [COLLABORATE PIS Part 1]	1.0	15 August 2025
Participant information sheet (PIS) [COLLABORATE PIS Part 2]	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]	1.0	21 August 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]		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Learning

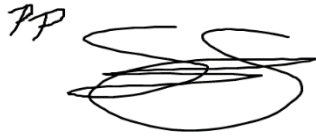
We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS project ID: 337660

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

A handwritten signature in black ink, consisting of the letters 'PP' followed by a large, stylized, cursive flourish that loops around and ends with a horizontal stroke.

Dr Paul Gorczynski
Chair

E-mail: bloomsbury.rec@hra.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

“After ethical review – guidance for researchers” [[SL-AR2 for other studies](#)]

Copy to: Ms Ruth Nicholson

Lead Nation England: approvals@hra.nhs.uk

London - Bloomsbury Research Ethics Committee

Attendance at Committee meeting on 01 October 2025

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Miss Priscilla Bekoe	Critical Care Nurse	No	
Mrs Ira Bhattacharya	Trustee/Board Member	Yes	
Ms Victoria Cover	Assistant Director	Yes	
Ms Dagmar Gauweiler	Senior Quality Assurance Auditor for Pharmacovigilance	No	
Dr Paul Gorczynski	Chartered Psychologist	Yes	Chair
Mr Tony Hoolaghan	Retired Chief Operating Officer	No	
Mr Alexandros Koumantos	Quality Assurance Pharmacist	No	
Dr Mary Lowth	General Practitioner / Medicolegal doctor	Yes	
Mrs Claire McLaughlan	Learning and Development Manager	Yes	
Dr Enrico Pagani	Medical Distributor/Responsible Person	No	
Dr Katy Peters	Senior Lecturer	Yes	
Dr Andy Petros	Consultant Paediatric Intensivist	Yes	
Dr Jay Tatla	Previous Study Start-Up & Regulatory Specialist II	Yes	
Mr Christopher Whitehouse	Chair and Managing Director	No	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Kevin Ahmed	Approvals Manager
Ms Sarah Ferry	Approvals Administrator
Simon Fisher	Approvals Administrator
Helen Penistone	Approvals Manager