



Health Research Authority

London - Bloomsbury Research Ethics Committee

Health Research Authority
2 Redman Place
Stratford
London
E20 1JQ

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

29 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

Thank you for your letter of 22 October 2025. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 08 October 2025

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
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
Covering letter on headed paper [COLLABORATE REC Cover Letter]		22 October 2025
Letters of invitation to participant [COLLABORATE Verbal Consent Statement]	2.0	22 October 2025
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]		
Participant consent form [COLLABORATE Verbal Consent Statement]	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 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
Research protocol or project proposal [COLLABORATE Protocol]	2.0	22 October 2025

Approved documents

The final list of approved documentation for the study is therefore as follows:

<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]	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
Covering letter on headed paper [COLLABORATE REC Cover		22 August 2025

Letter]		
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
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
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]		
Participant consent form [COLLABORATE Sub-Study ICF]	1.0	15 August 2025
Participant consent form [COLLABORATE Verbal Consent Statement]	2.0	22 October 2025
Participant information sheet (PIS) [COLLABORATE Sub-Study PIS Part 1]	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
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]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

IRAS Project ID: 337660

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in black ink, appearing to be 'S Fisher', with a large, stylized 'S' and a horizontal line through it.

Simon Fisher
Approvals Administrator

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

Copy to: Ms Ruth Nicholson

Lead Nation England: approvals@hra.nhs.uk