

22nd October 2025

Dear Bloomsbury Research Ethics Committee,

Subject: REC application for COLLABORATE Study

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

EDGE No.: 181495

REC Reference: 25/LO/0697

IRAS ID: 337660

Sponsor: Imperial College London

I am writing on behalf of Professor Neena Modi in response to the committees request for further information for the COLLABORATE 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	Section 'Will my baby benefit from taking part?' has been revised. We have retained the mention of possible inclusion benefit because this approach has been accepted by the HRA as valid for comparative effectiveness trials. Please see: Gale C, Hyde MJ, Modi N; WHEAT trial development group. Research ethics committee

	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>.	decision-making in relation to an efficient neonatal trial. Arch Dis Child Fetal Neonatal Ed. 2017 Jul;102(4 previously):F291-F298. doi: 10.1136/archdischild-2016-310935. Epub 2016 Sep 14. PMID: 27630188; PMCID: PMC5537508). Here we showed that a majority of UK RECs accepted that to mention possible inclusion benefit in comparative effectiveness trials is a component of an honest explanation of risks and benefits; i.e., inclusion benefit is a benefit so should be brought to a parent’s attention. Please also note the guidance to REC issued by the HRA following this study. We attach the paper, feedback document for RECs and response to REC from the HRA. Section ‘How will we find the answers?’ updated to include lay explanation of randomisation.
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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.	Removed fair and choice throughout Removed fair and choice throughout Updated to ‘wonder if’ in Randomisation and COLLABORATE study videos
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In addition, please provide the following information in order to clarify points raised in the assessment of the application

Assessment - Further Information Required	Response from the applicant
-Please clarify/justify why the Privacy notice on PIS 2 is not on PIS 1. Is this because the data	The PIS has been designed in two parts following feedback from parents regarding keeping information as short

is taken from the National Neonatal Research Database? Are there any GDPR issues the parents need to know about?	as possible: Parents receive Part 1 when they are initially approached. They only need to have the further information in Part 2 if they express interest in participation.
-Please include a clear definition for the end of the study. This should be descriptive rather than a date or timeframe. In most cases this will be the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection described in the protocol.	Definition reworded in the trial protocol to clarify it is when the last data is received. We have added minor admin changes to include the Trial Manager name, and REC reference.

Please note that we have also made minor revisions to the verbal consent statement and PIS Part 1 to correct small errors identified during the updates requested by the committee. These revisions have been provided with tracked changes for your review.

Please find the study documents attached for the Committee's consideration:

Document	Version	Date
COLLABORATE Animation Text (clean and tracked)	2.0	22/10/2025
Randomisation Animation Text (clean and tracked)	2.0	22/10/2025
COLLABORATE Parent Information Sheet Part 1 (clean and tracked)	2.0	22/10/2025
COLLABORATE Parent Information Sheet Part 2 & Privacy Notice (clean and tracked)	2.0	22/10/2025
COLLABORATE Protocol (clean and tracked)	2.0	22/10/2025
COLLABORATE Verbal Consent Statement	2.0	22/10/2025

Please do not hesitate to contact me should you require any additional information for this application.

Yours sincerely,

Alex Baker

ICTU Portfolio Manager

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