

22nd August 2025

Dear 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

IRAS ID: 337660

Sponsor: Imperial College London

I am writing on behalf of Professor Neena Modi to submit the Ethics Application for the COLLABORTAE study. Please find the documents attached for the Committee's consideration:

Document	Version	Date
COLLABORATE IRAS	N/A	22/08/2025
NIHR funding award letter	N/A	08/01/2025
COLLABORATE SoECAT	1.0	02/05/2025
COLLABORATE Organisation Information Document_Non Commercial	1.0	05/08/2025
COLLABORATE Organisation Information Document_Non Commercial_Edinburgh	1.0	05/08/2025
COLLABORATE mNCA	1.0	07/08/2025
COLLABORATE mNCA_Edinburgh	1.0	07/08/2025
Chief Investigator CV	N/A	Feb 2025
Imperial College London Civil Liability Insurance Certificate	N/A	04/08/2025
Sponsor Acknowledgment Letter	N/A	21/08/2025
COLLABORATE Protocol	1.0	21/08/2025
COLLABORATE Parent Information Sheet Part 1	1.0	15/08/2025
COLLABORATE Parent Information Sheet Part 2 & Privacy Notice	1.0	15/08/2025
COLLABORATE Verbal Consent Statement	1.0	15/08/2025
COLLABORATE Parent Information Sheet – Mechanistic Sub-Study	1.0	15/08/2025
COLLABORATE Informed Consent Form – Mechanistic Sub-Study	1.0	15/08/2025
COLLABORATE GP letter – Mechanistic Sub-Study	1.0	15/08/2025
COLLABORATE Text for study website	1.3	01/01/2025
Randomisation Animation Text	1.3	29/04/2025
COLLABORATE Animation Text	1.3	04/04/2025
NNRD Animation Text	1.2	04/04/2025
COLLABORATE Flyer 1 (pink theme)	2.3	04/04/2025

Document	Version	Date
COLLABORATE Flyer 1 (yellow theme)	2.3	04/04/2025
COLLABORATE Animation Flyer 2 (pink human theme)	1.3	04/04/2025
COLLABORATE Animation Flyer 2 (yellow human theme)	1.3	04/04/2025
PARCA-R questionnaire	N/A	09/06/2025
COLLABORATE Cot Card Pending Randomisation 1 Labels	1.0	15/08/2025
COLLABORATE Cot Card Pending Randomisation 2 Labels	1.0	15/08/2025
COLLABORATE Cot Card – Randomisation 1 - pHDM	1.0	15/08/2025
COLLABORATE Cot Card – Randomisation 1 - Formula	1.0	15/08/2025
COLLABORATE Cot Card – Randomisation 2 - Fortifier	1.0	15/08/2025
COLLABORATE Cot Card – Randomisation 2 – Treatment as usual	1.0	15/08/2025
COLLABORATE Paper Notes Consent Randomisation 1 Labels	1.0	15/08/2025
COLLABORATE Paper Notes Consent Randomisation 2 Labels	1.0	15/08/2025
COLLABORATE Paper Notes – Randomisation 1 - pHDM	1.0	15/08/2025
COLLABORATE Paper Notes – Randomisation 1 - Formula	1.0	15/08/2025
COLLABORATE Paper Notes – Randomisation 2 - Fortifier	1.0	15/08/2025
COLLABORATE Paper Notes – Randomisation 2 – Treatment as usual	1.0	15/08/2025

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

Yours sincerely,
Alex Baker

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