

Professor Neena Modi
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Email: postawardsetup@nihr.ac.uk
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Dear Professor Modi

EME Project: NIHR163188 – COLLABORATE: An efficient, UK-wide, real-world-data-enabled, group-sequential, randomised controlled trial to determine clinical efficacy, effect size, and safety of widely used enteral feeds in reducing necrotising enterocolitis, mortality, and cognitive impairment in extremely preterm babies

Thank you for responding to the concerns raised by the Funding Committee. Following consideration of your revised application dated 13 December 2024, I am pleased to inform you that your above-titled proposal has been recommended for funding. Please would you inform your co-applicants of the decision.

Revised Application Signatures

We are unable to raise a contract without receiving an updated set of electronic signatures from those in key supporting roles (e.g. Head of Department, Finance Office and Sponsor) confirming approval of your revised stage 2 application form and detailed research plan.

Once you have confirmed that your list of signatories is correct, and all signatories have 'accepted' their invitation, they will be asked to provide their signature.

Contracting Information

We also need the following information to draw up your contract. This is requested in the 'Contracting Information' task assigned to you in REALMS:

https://realms.nihr.ac.uk/s_Login.jsp

More detail is provided in the 'Contracting Information' task but in summary the information requested asks for:

- The name of the lead applicant acting as REALMS admin lead for the project. (This question is applicable only if there are joint lead applicants so that we know who to assign 'tasks' to in our management system)
- Confirmation of your start date
- Contact details for the person the contract should be sent to for signature. Note that in most cases this will be electronic signature via DocuSign

- Contact details for the person who should be listed as the 'Contractor's Representative' on the contract.
- Acknowledgements relating to the Researcher Development Concordat, and compliance with the NIHR safeguarding policy

Please log into REALMS and complete this task as soon as possible.

Clinical Trials

Trials involving medicinal products must comply with 'The Medicines for Human Use (Clinical Trials) Regulations 2004'. You have indicated on your full proposal that your sponsor will be Imperial College London

and we will assume that this is still the case unless we hear from you. The Department of Health and Social Care find this nomination acceptable but they reserve the right to refuse this nomination at a later date if they are not satisfied with the arrangements put in place to conduct the trial.

UKCRC Registered CTU Network offers a one day workshop designed for current and aspiring Chief Investigators, to empower you to excel in the conduct of clinical trials through effective collaboration with a clinical trials unit:

<https://ukcrc-ctu.org.uk/how-to-be-a-good-chief-investigator-for-clinical-trials-one-day-workshop>

Start-Up Information

I will be contacting you again soon to request further key project information to facilitate the timely start-up of your study.

Please note that for primary research studies that have supplied an IRAS ID, key data is shared between REALMS and the Clinical Research Network CPMS to assist with review of eligibility for CRN support.

Publicising Your Project

Please note that this award is not secure until the work has been contracted. Therefore, you must not publicise this award until you receive a fully executed contract from us.

After the contracts have been signed we encourage successful applicants to consider submitting their protocols to journals for review; should you do so, please remember to submit an output notification via the REALMS.

Congratulations, and we wish you all success with your project.

If you have any queries please contact me on postawardsetup@nihr.ac.uk.

Yours sincerely,

Sally Hickman

The Efficacy and Mechanism Evaluation (EME) Programme