

Department of Research and Development
 Research Delivery Team Office
 Unit G3, Harbour Yard
 Chelsea Harbour
 London
 SW10 0XD

1st December 2015

Professor Neena Modi
 Professor of Neonatal Medicine
 Imperial College London, Section of Neonatal Medicine
 4th Floor, Lift Bank D

Dear Neena,

Notification of NHS Permission (R&D Approval)

Study title: eNewborn: European Neonatal Benchmarking and Evaluation Programme
IRAS reference: 185457
REC reference: 15/WM/0344
Local reference: C&W15/103

I am pleased to inform you that the department of research and development review of the above project is now complete, and the project has been formally approved to be undertaken at Chelsea and Westminster Hospital NHS Foundation Trust under the terms of the enclosed Site Investigator Agreement. The documents reviewed are as follows:

Document	Version	Date
REC Favourable Opinion Letter		15/09/2015
R&D Form	185457/841815/14/925	02/09/2015
Protocol	1.0	31/07/2015
Consent Form	1.0	31/07/2015
Letter NNU UK	1.0	31/07/2015
Data Items for Study	1.0	31/07/2015
Letter from Sponsor		01/09/2015
Site Investigator Agreement		06/10/2015

As you may be aware, the Trust is committed to achieving the national metric of recruiting the first participant promptly and finishing recruitment on time and on target. These metrics are reported to the Department of Health and published on our website, and there are financial penalties if we fail to achieve them. Therefore, your targets are:

Recruitment of first participant by:	8 th February 2015
Recruitment of participants by:	1 st November 2025

Please notify the department of research and development of the date you consent your first participant.

NHS Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, GCP and applicable NHS Trust policies and procedures. Research Standard Operating Procedures are available to download from the intranet or can be requested by emailing research.development@chelwest.nhs.uk.

NHS Permission applies for the duration of the research except where action is taken to suspend or terminate the approval early. Where the duration of the study is to be extended beyond the period specified in the Site Specific Information (SSI) form, you must notify the department of research and development prior to the extension. Also please be reminded that you must notify us of any amendments and the study closure.

Please note that Chelsea and Westminster Hospital NHS Foundation Trust is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research.

I wish you well in your research. Please do not hesitate to contact us should you need any guidance or assistance.

Yours sincerely



Dr Essam Ramhamadany
Assistant Director of Research and Development
Chelsea and Westminster Hospital NHS Foundation Trust

Enc. Site Investigator Agreement