

Professor Neena Modi
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06/01/2014 (reissued 04/02/2014 to correct REC Reference only)

Dear Professor Neena Modi

R&D Number: C&W14/001

IRAS ID: 133075

REC Ref: 13/SW/0339

Study Title: iNeo: The International Network for Evaluating Outcomes of Very Low Birth Weight and Very Preterm Neonates: Collaborative Comparisons of International Health Services for Quality Improvement in Neonatal Care

I am pleased to inform you that the R&D 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 (with conditions)		3 rd January 2014
REC Form	133075/543721/1/361	19 th December 2013
Protocol	1	14 th December 2013
Letter of Invite	1	14 th December 2013
Summary CV for Professor Neena Modi		14 th December 2013
Letter from Funder		1 st February 2013

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. R&D standard operating procedures are available to download from the intranet or can be requested by emailing research.development@chelwest.nhs.uk.

The R&D approval 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 R&D Support Office prior to the extension. Also please be reminded that you must notify us of any amendments and the study closure.

Please note that the NHS organisation 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

A handwritten signature in blue ink, appearing to read 'D McLean', with a large circular flourish at the beginning.

Donna McLean
Research Operations Manager