



Health Research Authority

East Midlands - Leicester South Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
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Telephone: 0207 104 8372

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

18 June 2021

Dr Cheryl Battersby
Clinical Senior Lecturer and Honorary Consultant Neonatologist
Chelsea & Westminster Hospital
369 Fulham Road
Chelsea and Westminster Hospital Imperial College campus
SW10 9NH

Dear Dr Battersby

Study title: neoWONDER: Neonatal Whole Population Data linkage approach to improving long-term health and wellbeing of preterm and sick babies
REC reference: 21/EM/0130
Protocol number: 1.0
IRAS project ID: 293603

Thank you for your response. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 02 June 2021

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Other [Responses to REC amendment]	1.0	16 June 2021
Participant information sheet (PIS) [Patient notification amended]	2.0	16 June 2021

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [cover letter]	1.0	10 May 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Verification certificate]	1.0	07 May 2021
IRAS Application Form [IRAS_Form_10052021]		10 May 2021
IRAS Application Form XML file [IRAS_Form_10052021]		10 May 2021
IRAS Checklist XML [Checklist_18062021]		18 June 2021
Letter from funder [Letter from funder]		25 March 2020
Letter from sponsor [Imperial College sponsorship letter]	1.0	07 May 2021
Letters of invitation to participant [Invitation to neonatal units]	1.0	29 April 2021
Other [Responses to REC amendment]	1.0	16 June 2021
Participant information sheet (PIS) [Patient notification amended]	2.0	16 June 2021
Referee's report or other scientific critique report [Peer review 1]		29 April 2021
Referee's report or other scientific critique report [Peer review 2]	1.0	29 April 2021
Research protocol or project proposal [neoWONDER REC Protocol]	1.0	24 March 2021
Schedule of Events or SoECAT [SoECAT submitted at the time of funding application (no change)]	1.0	06 December 2019
Summary CV for Chief Investigator (CI) [CV]		21 April 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Data flow]	1.0	24 March 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Appendix Cohorts]	1.0	24 March 2021

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

IRAS Project ID: 293603	Please quote this number on all correspondence
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Yours sincerely

Philip Evans

Philip Evans

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Copy to: Miss Ruth Nicholson
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