Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Cheryl Battersby
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30 June 2021

Dear Dr Battersby

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**neoWONDER: Neonatal Whole Population Data linkage approach to improving long-term health and wellbeing of preterm and sick babies**
IRAS project ID:	**293603**
Protocol number:	**1.0**
REC reference:	**21/EM/0130**
Sponsor	**Head of Research Governance and Integrity, Imperial College**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **293603**. Please quote this on all correspondence.

Yours sincerely,

Helen Poole
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Miss Ruth Nicholson*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
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
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
Response to Additional Conditions Met		
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

IRAS project ID	293603

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
This is a single site study therefore there is only one site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	No study funding will be provided to sites as per the Organisational Information Document.	The Chief Investigator will be responsible for all research activities performed at study sites of this type.	Use of identifiable patient records held by an NHS organisation to identify potential participants should be undertaken by a member of the direct care team for the patient, so it would not normally be acceptable for this to be done by staff not employed by that organisation.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they do intend to apply for inclusion on the NIHR CRN Portfolio.