East Midlands - Leicester South Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0207 1048310

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

02 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**

The Research Ethics Committee (REC) reviewed the above application at the meeting held on 27 May 2021. Thank you for attending to discuss the application.

Ethical opinion: Favourable Opinion with Additional Conditions

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four

elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Number	Condition	Response from the applicant
1	**Make the following change to the Participant Information Sheet (PIS) [patient notification]:**	
1a	Page 1: Reinstate the specific names of the third parties rather than saying "trusted third party, such as NHS digital". This was discussed a t the meeting and whilst the applicants said that parents were against having too much detail, the Committee require specific detail to be included.	
1b	Page 2: Change "Taking part in the research is entirely voluntary" to reflect that the study will happen unless the parent opts out or simply remove entirely, as the study is not voluntary.	
1c	Page 3: Reword "Findings from this research may benefit your child" given the conversation with the REC that you should not overstate and as research, it would be difficult to promise a direct benefit to the parent's child immediately as a result of their participation.	
1d	Ad text to say that the data from the study will contribute towards the doctorate qualification of [and name the students] and briefly describe their role in the study.	
1e	Add in a new section entitled "who has reviewed this study", to say that the study has been reviewed and granted favourable opinion by the Leicester South Research Ethic Committee.	

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym

for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland)being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The documents reviewed and approved at the meeting were:

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
IRAS Application Form XML file [IRAS_Form_10052021]		10 May 2021
IRAS Checklist XML [Checklist_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
Participant information sheet (PIS) [Patient notification]	1.0	15 April 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

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 293603	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Mrs Jeanne-Anna Charly
Chair
E-mail: leicestersouth.rec@hra.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers" [SL-AR2 for other studies]

East Midlands - Leicester South Research Ethics Committee

Attendance at Committee meeting on 27 May 2021

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Georgie Bennett	Volunteer	Yes	
Mr Derek Butters	Industrial Pharmacy Consultant and Locum Pharmacist	No	
Mrs Jeanne-Anna Charly	Retired State Registered Nurse/Teacher	Yes	Chair
Dr Brian Hands	Retired General Practitioner	Yes	
Dr Brendan Laverty	Retired Head of Research Governance	Yes	
Ms Rachel Neilan	Volunteer	Yes	
Dr Derek Prater	Pharmacist	Yes	
Miss Niamh Quann	Trial Manager	Yes	
Mrs Sarah Elizabeth Westwater-Wood	Lecturer	No	

Also in attendance:

Name	*Position (or reason for attending)*
Kathryn Carter	Observer and Retired Pharmacist
Mrs Emma Cramp	Observer and Clinical Pharmacist
Dr Sarah Graves	Approvals Officer
Mrs Helen Poole	Approvals Specialist