Health Research Authority
Yorkshire & The Humber - Leeds East Research Ethics Committee
NHSBT Newcastle Blood Donor Centre
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Newcastle upon Tyne
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Telephone: 0207 104 8018

11 December 2020

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

Dear Dr Battersby

Study title:	**Parent and patient perspectives on linkage between existing data to evaluate long-term health and wellbeing of preterm babies**
REC reference:	**20/YH/0330**
Protocol number:	**1.1**
IRAS project ID:	**291612**

Thank you for your email of 4th December 2020, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved on behalf of the PR sub-committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a **favourable ethical opinion** for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

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

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

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. 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/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

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 HRA 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

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

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Poster]	1.1	28 October 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance letter]	1	05 August 2020
Initial Assessment for REC [Generated by HARP system]		
Interview schedules or topic guides for participants	1.1	18 October 2020
IRAS Application Form [IRAS_Form_09112020]		09 November 2020
IRAS Checklist XML [Checklist_09112020]		09 November 2020
Letter from funder [NIHR advanced fellowship award]	1	04 March 2020

Letter from sponsor	1	06 November 2020
Other [Response to provisional opinion]	1	03 December 2020
Participant consent form	1.1	28 October 2020
Participant consent form	1.2	02 December 2020
Participant information sheet (PIS) [PIS Survey]	1.2	02 December 2020
Participant information sheet (PIS) [Interview PIS]	1.2	02 December 2020
Referee's report or other scientific critique report [Peer review]	1	
Referee's report or other scientific critique report [Peer reviewer 2]	1	
Research protocol or project proposal [Protocol]	1.1	28 October 2020
Summary CV for Chief Investigator (CI)	1	
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [Sponsor letter]	1	06 November 2020
Validated questionnaire [Survey]	1.1	28 October 2020
Validated questionnaire [Survey]	1.2	02 December 2020

Statement of compliance

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: 291612 **Please quote this number on all correspondence**

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

Yours sincerely
pp

Miss Kate Woodrow
Chair

Email: leedseast.rec@hra.nhs.uk

Yorkshire & The Humber - Leeds East Research Ethics Committee

Attendance at Chair's Actions meeting in correspondence

Committee Members:

Name	*Profession*	*Present*
Miss Kate Woodrow	Chief Pharmacist	Yes