Health Research Authority

North East - Newcastle & North Tyneside 2 Research Ethics Committee

NHS BT Blood Donor Centre
Holland Drive
Newcastle upon Tyne
Tyne and Wear
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Telephone: 0207 972 2503

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

30 March 2020

Professor Jennifer J Kurinczuk
Professor of Perinatal Epidemiology, Director, National Perinatal Epidemiology Unit, Director, NIHR Policy Research Unit in Maternal and Neonatal Health and Care
University of Oxford
National Perinatal Epidemiology Unit
University of Oxford Old Road Campus
Headington, Oxford
OX3 7LF

Dear Professor Kurinczuk

Study title:	**Neonatal Complications of Coronavirus Disease (COVID-19) Study**
REC reference:	**20/NE/0107**
IRAS project ID:	**282127**

The Research Ethics Committee reviewed the above application at the meeting held on 30 March 2020. Thank you for attending to discuss the application.

Ethical opinion

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. .

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
1	Include on the webpage that patient identifiable data will not be used in the writing up of results/reports
2	Poster to detail (briefly) what information is being collected and how it might be used

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

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/

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

NHS/HSC Sites

The favourable opinion applies to all NHS/HSC sites taking part in the study 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*
Copies of advertisement materials for research participants [Information poster]	V1	25 March 2020
Covering letter on headed paper [Invitation letter to doctor]		25 March 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance letter]		01 August 2019
IRAS Application Form [IRAS_Form_26032020]		26 March 2020
IRAS Application Form XML file [IRAS_Form_26032020]		26 March 2020
IRAS Checklist XML [Checklist_26032020]		26 March 2020
Letter from funder [Funder letter]		23 March 2020
Letter from sponsor [Sponsor letter]		25 March 2020
Non-validated questionnaire [Data collection sheet]	V6	25 March 2020
Other [Data analysis plan]	V1	25 March 2020
Other [Data flow diagram]	V1	25 March 2020
Other [Webpage information]	V1	25 March 2020
Other [Privacy notice]	V1	25 March 2020
Other [Bliss letter of support]	V1	20 March 2020
Other [Sands letter of support]	V1	17 March 2020
Other [Doctor reminder letter]	V1	25 March 2020
Other [Doctor thank you letter]	V1	25 March 2020
Other [ICO registration]	V1	12 September 2019
Other	1	30 March 2020
Participant information sheet (PIS) [Parent information leaflet]	V1	25 March 2020
Research protocol or project proposal [Study protocol]	V1	25 March 2020
Summary CV for Chief Investigator (CI) [CV CI]		25 March 2020

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: 282127	**Please quote this number on all correspondence**

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

Yours sincerely

Catherine Adams Approvals Manager on behalf of

Professor Andy Hall
Chair

E-mail: newcastlenorthtyneside2.rec@hra.nhs.uk

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

Copy to: N/A N/A CTRG
Confidentiality Advice Team

North East - Newcastle & North Tyneside 2 Research Ethics Committee

Attendance at Committee meeting on 30 March 2020

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Joan Bedlington	Charity Manager	Yes	
Dr Helen Brittain (Chair)	Clinical Psychologist Retired	Yes	
Mrs Sunder Chita		Yes	
Mrs Kathryn Gillanders	Retired Head of Clinical Research	Yes	
Professor Andy Hall	Former Associate Dean for Bio Resources	Yes	
Miss Phillipa Hearty	Research Assistant	Yes	
Dr Michael Millar	Consultant in Infection (Barts Health)	Yes	
Dr Tony Newton	Director	Yes	