East of Scotland Research Ethics Service (EoSRES)

Research Ethics Service

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

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Dr Jessica Fleminger
Department of Women and Children's Health
10th Floor North Wing
St Thomas' Hospital
London
SE1 7EH

Date: 27 May 2021
Your Ref:
Our Ref: LR/**21/ES/0061**
Enquiries to: Mrs Lorraine Reilly
Direct Line: 01382 383878
Email: tay.eosres@nhs.scot

Dear Dr Fleminger

Study title:	**An investigation of the neonatal burden of disease of hypertensive disorders of pregnancy: a population-based study using the National Neonatal Research Database**
REC reference:	**21/ES/0061**
Protocol number:	**21IC6828**
IRAS project ID:	**295875**

The Proportionate Review Sub-committee of the East of Scotland Research Ethics Service REC 1 reviewed the above application on 27 May 2021.

Ethical opinion

On behalf of the Research Ethics Committee (REC), the sub-committee 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.

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.

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

The favourable opinion applies to all NHS 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").

Approved documents

The documents reviewed and approved were:

Document	Version	Date
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsorship indemnity]		05 August 2020
IRAS Application Form [IRAS_Form_12052021]		12 May 2021
Letter from funder [Funding letter]		04 May 2021
Letter from sponsor [Sponsorship letter]		11 May 2021
Letters of invitation to participant [Letter to neonatal units opt-out]		
Research protocol or project proposal [HDP protocol]	1.1	19 March 2021
Summary CV for Chief Investigator (CI) [Summary CV (Dr Cheryl Battersby)]		
Summary CV for student [Student CV (Dr Frances Conti - Ramsden)]		
Summary CV for student [Student CV (Jessica Fleminger)]		
Summary CV for supervisor (student research) [Supervisor CV (Professor Lucy Chappell)]		02 May 2021

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

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/

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

IRAS project ID: 295875 Please quote this number on all correspondence

Yours sincerely

pp
Dr Robert Rea
Chair

Email: tay.eosres@nhs.scot

Enclosures: List of names and professions of members who took part in the review
After ethical review – guidance for researchers

Copy to: Mr Keith Boland
Dr Cheryl Battersby, Imperial College London

East of Scotland Research Ethics Service REC 1

Attendance at PRS Sub-Committee of the REC meeting on 27 May 2021

Committee Members:

Name	Profession	Present	Notes
Dr Robert Rea	Head of Innovation	Yes	Chair
Dr Ian Barker	Retired Anaesthetist	Yes	
Mrs Katherine Coll	Trial Manager & Senior Non-Commercial R&D Administrator	Yes	

Also in attendance:

Name	Position (or reason for attending)
Mrs Lorraine Reilly	REC Manager