



Health Research Authority

London - Queen Square Research Ethics Committee

HRA NRES Centre Bristol
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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 2020 Reissued 05 June 2020

Dr Cheryl Battersby
Chelsea and Westminster Hospital
369 Fulham Road
London
SW10 9NH

Dear Dr Battersby

Study title: Management of Patent Ductus Arteriosus in babies admitted to UK neonatal units: a population-based study using the National Neonatal Research Database

REC reference: 20/LO/0825

Protocol number: 1.1

IRAS project ID: 284040

The Proportionate Review Sub-committee of the London - Queen Square Research Ethics Committee reviewed the above application.

Ethical opinion

On behalf of the Committee, 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.

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/>

For research studies related to COVID-19, we are fast-tracking the publication of research summaries. 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 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>	
IRAS Application Form [IRAS_Form_18052020]		18 May 2020	
Research protocol or project proposal [Protocol]	1	12 May 2020	
Summary CV for Chief Investigator (CI) [CV CI]	1	12 May 2020	
Summary CV for student [Summary CV for student - Derek Chan]			
Summary CV for supervisor (student research) [Summary CV for supervisor - Chris Gale]		11 September 2019	

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/>

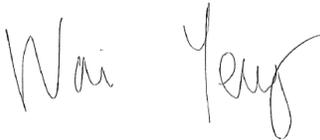
HRA Learning

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: 284040	Please quote this number on all correspondence
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Yours sincerely



PP - Mr Eamonn Walsh
Chair

Email: queensquare.rec@hra.nhs.uk

Enclosures: List of names and professions of members who took part in the review

“After ethical review – guidance for researchers”

Copy to: Miss Ruth Nicholson
Dr Cheryl Battersby

London - Queen Square Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>	
Dr Ciaran Scott Hill	Neurosurgery Speciality Registrar	Yes		
Ms Eleanor Rose Lees-Millais	Clinical Standards Administration	Yes		
Dr Eamonn Walsh	Senior Lecturer and Programme Lead for MSc Neuroscience	Yes		

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>	
Mr Wai Yeung	Approvals Administrator	