Health Research Authority

Yorkshire & The Humber - Sheffield Research Ethics Committee

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Tel: 0207 104 8082

15 April 2019

Dr Don Sharkey
Associate Professor of Neonatal Medicine
University of Nottingham
Academic Child Health
School of Medicine, University of Nottingham
E Floor East, QMC, Nottingham
NG7 2UH

Dear Dr Sharkey

Study title:	**Respiratory outcomes of infants <32 weeks gestation – risk factors for bronchopulmonary dysplasia**
REC reference:	**19/YH/0115**
IRAS project ID:	**259802**

The Research Ethics Committee reviewed the above application at the meeting held on 1 April 2019. Thank you for being available on the telephone to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

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.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission 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, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

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 clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non-registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study 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" below).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]	1	01 March 2019
Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only) [insurance]	1	31 July 2018
Letter from sponsor [Sponsor letter]	1	11 March 2019
REC Application Form [REC_Form_13032019]		13 March 2019
Research protocol or project proposal [Protocol]	1	01 March 2019
Summary CV for Chief Investigator (CI) [CV for CI]	1	01 March 2019
Summary CV for student [Student CV]	1	01 March 2019
Summary CV for supervisor (student research) [2nd supervisor CV]	1	11 March 2019

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.

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.

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

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/

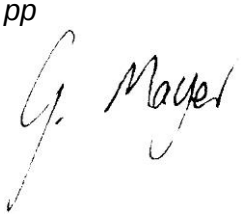
HRA Learning

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/

19/YH/0115	**Please quote this number on all correspondence**

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

Yours sincerely
pp



Professor Basil Sharrack
Chair

E-mail: nrescommittee.yorkandhumber-sheffield@nhs.net

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 researcher' SL-AR2
Copy to:	Ms Angela Shone – Research Dept, University of Nottingham
	Mr Saleh Algarni – School of Medicine, University of Nottingham
	Lead Nation - England

Yorkshire & The Humber - Sheffield Research Ethics Committee

Attendance at Committee meeting on 1 April 2019

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Paul Bacon	Lead Clinical Scientist in Audiological Science, Medical Physics	No	
Mrs Jacqui Gath	Retired Senior Systems Analyst	Yes	
Professor Frank Jones	Retired Professor of Polymers and Composites	Yes	
Mr Pete Laud	Statistical Consultant	Yes	
Mr Richard Lindley	Consultant Paediatric Surgeon	No	
Dr Marie Marron	BHF Research Fellow	No	
Dr Amaka Offiah (Vice Chair)	Reader in Paediatric Musculoskeletal Imaging	No	
Mrs Brenda Riley	Retired IT Trainer	Yes	
Professor Basil Sharrack (Chair)	Consultant Neurologist	Yes	
Dr Soon Song	Consultant Diabetologist	No	
Mrs Aikaterini Staikoura-Wilson	Pharmacist	No	
Mrs Yvonne Stephenson	Lead Technician in the Department of Infection and Immunity	Yes	
Mrs Helen Teasdale	University Executive Assistance	No	
Dr Steven Thomas	Consultant Vascular and Cardiac Radiologist	No	
Dr Liz Williams (Alternate Vice Chair)	Senior Lecturer in Human Nutrition	No	
Mr John de Bartolome (co-opted member)	Retired Insurance Broker	Yes	
Dr Jane McKeown (co-opted member)	University Teacher	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Gillian Mayer	Approvals Officer
Christie Ord	Approvals Specialist
Helen Penistone	Approvals Specialist