Health Research Authority

South Central - Oxford A Research Ethics Committee
Bristol Research Ethics Committee Centre
Whitefriars
Level 3 Block B
Lewins Mead
Bristol
BS1 2NT

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

12 February 2020

Dr Mark J Johnson
Honorary Senior Lecturer
University of Southampton and University Hospital Southampton NHS Trust
Neonatal Unit
University Hospital Southampton NHS Foundation Trust
Coxford Road
SO16 5YA

Dear Dr Johnson

Study title:	**Reassessing the growth of infants born below 32 weeks' gestation in the UK, 2014-2018**
REC reference:	**20/SC/0073**
Protocol number:	**CHI1013**
IRAS project ID:	**266642**

The Proportionate Review Sub-committee of the South Central - Oxford A Research Ethics Committee reviewed the above application on 17 February 2020.

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.

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/

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:

Document	*Version*	*Date*
IRAS Application Form [IRAS_Form_29012020]		29 January 2020
IRAS Checklist XML [Checklist_29012020]		29 January 2020
Letter from sponsor [Sponsorship Letter]	1	18 June 2019
Research protocol or project proposal [Protocol]	5	14 January 2020
Summary CV for Chief Investigator (CI) [Johnson CV]	1	06 May 2017
Summary CV for student [Student CV]	1	01 November 2019
Summary CV for supervisor (student research) [Johnson CV]	1	06 May 2017

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/

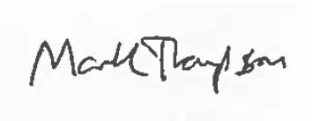
HRA Learning

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.

20/SC/0073	**Please quote this number on all correspondence**

Yours sincerely



On behalf of Dr Hugh Davies
Chair

Email: nrescommittee.southcentral-oxforda@nhs.net

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

"After ethical review – guidance for researchers" [SL-AR2]

Copy to: Ms Natasha Chigbo, University of Southampton NHS Foundation Trust

South Central - Oxford A Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 17 February 2020

Committee Members:

Name	*Profession*	*Present*	*Notes*
Ms Jane Cheeseman	Research Nurse	Yes	
Dr Hugh Davies (Chair)	Consultant Paediatrician / HRA Training Adviser	Yes	
Dr Fraser Macfarlane	Retired Senior Lecturer - Health Care Management	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mark Thompson	Approvals Officer