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Email: hra.approval@nhs.net
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14 February 2020

Dear Dr Johnson

HRA and Health and Care Research Wales (HCRW) Approval Letter

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

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **266642**. Please quote this on all correspondence.

Yours sincerely,

Joanna Strickland

Approvals Specialist

Email: nrescommittee.southcentral-oxforda@nhs.net

Copy to: *Ms Natasha Chigbo, University of Southampton NHS Foundation Trust*
Aneurin.young@nhs.net

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

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

IRAS project ID	266642

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
There is one NHS site type acting as a full research site, performing the research activities as described in the study protocol.	This is a single site study sponsored by the participating NHS organisation. You should work with your sponsor R&D office to make arrangements to set up the study. The sponsor R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.	As a single site, same sponsor study, there is an exemption from the Organisation Information Document and Schedule of Events for University Hospital Southampton NHS Foundation Trust A bespoke agreement will be in place between the sponsor and Chelsea and Westminster Hospital NHS Foundation Trust who is providing anonymised data from a database.	External funding has been secured from the NIHR Southampton Biomedical Research Centre. Funding is available to the NHS site providing the anonymised data.	A local Principal Investigator is expected to be in place to oversee the research activities.	As the researchers are already employees of the NHS Trust, a letter of access/honorary research contact is not required. Pre-engagement checks and occupational health clearance is not required for this data only study.