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Email: hra.approval@nhs.net
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27 August 2019

Dear Professor Macleod

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

Study title:	**National PReCePT (Prevention of cerebral palsy in pre-term labour) Programme Evaluation**
IRAS project ID:	**260504**
Protocol number:	**2019 - 2184**
REC reference:	**19/HRA/4874**
Sponsor	**Univerisity of Bristol**

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 attached document *"After HRA Approval – guidance for sponsors and investigators"* gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, 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 **260504**. Please quote this on all correspondence.

Yours sincerely,

Lauren Allen

Email: hra.approval@nhs.net

Copy to: *Mr Adam Taylor*

List of Documents

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

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]		01 August 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance letter]		12 August 2019
Interview schedules or topic guides for participants [Topic guide - midwife]		29 March 2019
Interview schedules or topic guides for participants [Topic guide - unit staff]		29 March 2019
Interview schedules or topic guides for participants [Topic guide - AHSN leads]		29 March 2019
IRAS Application Form [IRAS_Form_16082019]		16 August 2019
Letter from funder [Funding letter]		02 August 2019
Letters of invitation to participant [Invite letter]	2.0	10 June 2019
Participant consent form [Consent form]	1.0	02 August 2019
Participant information sheet (PIS) [Unit Staff Interviews]	3.0	22 August 2019
Participant information sheet (PIS) [AHSN Staff Interviews]	3.0	22 August 2019
Research protocol or project proposal [PReCePT Programme Evaluation Protocol]	1.1	02 August 2019
Summary CV for Chief Investigator (CI) [CV]		18 July 2019

IRAS project ID	260504

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
NHS organisations will act as Participant Identification Centres. The research will involve telephone interviews with NHS staff.	Organisations will not be required to formally confirm capacity and capability, and research procedures may begin 35 days after provision of the local information pack, provided the following conditions are met. • You have contacted participating NHS organisations (see below for details) • HRA and HCRW Approval has been issued	The sponsor intends to use a bespoke agreement with Participant Identification Centres.	Any funding arrangements will be detailed in the PIC agreement.	A key contact should be in place at PICs to liaise with regarding identification of potential participants.	Access arrangements will not be applicable as PIC activity will be conducted by local staff.

	• The NHS organisation has not provided a reason as to why they cannot participate • The NHS organisation has not requested additional time to confirm. You may start the research prior to the above deadline if HRA and HCRW Approval has been issued and the site positively confirms that the research may proceed. You should now provide the local information pack for your study to your participating NHS organisations. A current list of R&D contacts is accessible at the NHS RD Forum website and				

	these contacts MUST be used for this purpose. The password to access the R&D contact list is Redhouse1.				

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.