Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

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Email: hra.approval@nhs.net

23 August 2018

Dear Dr Luyt

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

Study title:	**PReCePT Study – A cluster randomised trial evaluating the impact of an enhanced support implementation of the PReCePT quality improvement toolkit to increase the uptake of magnesium sulphate in pre-term deliveries for the prevention of neurodisabilities**
IRAS project ID:	**242419**
Protocol number:	**CH/2017/6417**
REC reference:	**19/HRA/0323**
Sponsor	**University of Bristol Hospitals 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.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations in England and Wales that are not undertaking sponsorship responsibilities should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter. You should then work with each organisation that has confirmed capacity and capability and provide clear instructions when research activities can commence.

Participating NHS organisations in England and Wales that are undertaking sponsorship responsibilities **will not** be required to formally confirm capacity and capability before you may commence research activity at site. As such, you may commence the research at each organisation 35 days following sponsor provision to the site of the local information pack, so long as:

- You have contacted participating NHS organisations (see below for details)
- 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 the site positively confirms that the research may proceed.

If not already done so, 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. After entering your IRAS ID you will be able to access a password protected document (password: **White22**). The password is updated on a monthly basis so please obtain the relevant contact information as soon as possible; please do not hesitate to contact me should you encounter any issues.

Commencing research activities at any NHS organisation before providing them with the full local information pack and allowing them the agreed duration to opt-out, or to request additional time (unless you have received from their R&D department notification that you may commence), is a breach of the terms of HRA and HCRW Approval. Further information is provided in the "*summary of assessment*" section towards the end of this document.

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

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 the devolved administrations of 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) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

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.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?

You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Ms Pippa Craggs

Tel: 01173421246

Email: pippa.craggs@bristol.ac.uk

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 **242419**. Please quote this on all correspondence.

Yours sincerely

Juliana Araujo

Assessor

Email: hra.approval@nhs.net

Copy to: *Sponsor Representative: Ms Pippa Craggs, University Hospitals Bristol NHS Foundation Trust*

Lead NHS R&D Office Representative: Mrs Geraldine Salahi-Ali, University of Bristol Hospitals NHS Foundation Trust

List of Documents

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

Document	*Version*	*Date*
Contract/Study Agreement template [PReCePT Study Model Agreement]	1.0	17 August 2018
Covering letter on headed paper [PReCePT Study Invitation Cover Letter]	1.0	17 August 2018
HRA Schedule of Events [PReCePT Study Schedule of Events Validated]	1.0	17 August 2018
HRA Statement of Activities [PReCePT Study Statement of Activities Validated]	1.0	17 August 2018
Interview schedules or topic guides for participants [PReCePT Study Staff Interview Topic Guide]	1.0	17 August 2018
IRAS Application Form [IRAS_Form_17082018]		17 August 2018
IRAS Application Form XML file [IRAS_Form_17082018]		17 August 2018
IRAS Checklist XML [Checklist_17082018]		17 August 2018
Letter from funder [PReCePT Study Letter from Funder]	1.0	19 January 2018
Letter from sponsor [Sponsorship approval letter]	1.0	17 August 2018
Other [PReCePT Study CLAHRC West Letter of Support]	1.0	03 August 2018
Other [PReCePT Study WEAHSN Letter of Support]	1.0	07 August 2018
Other [PReCePT Study List of Eligible Units]	1.0	17 August 2018
Other [List of eligible sites.]		22 August 2018
Participant consent form [PReCePT Study Unit Consent Form]	1.0	17 August 2018
Participant information sheet (PIS) [PReCePT Study Unit Information Sheet]	1.0	17 August 2018
Participant information sheet (PIS) [PReCePT Study Staff Interview Information Sheet]	1.0	17 August 2018
Research protocol or project proposal [PReCePT Study Protocol]	1.0	17 August 2018
Summary CV for Chief Investigator (CI) [Dr Karen Luyt_CV]	1.0	13 July 2018

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	This study involves multiple research sites. A list of eligible participating NHS organisations was submitted separately.
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The sponsor proposes the use of an unmodified Model Agreement for Non-Commercial Research in the Health Service.
4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	The sponsor has secured funding from the Health Foundation. A copy of the grant agreement was submitted. Schedule 1 of the Statement of Activities outlines the funds and resources to be allocated to the research sites.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments

Section	Assessment Criteria	Compliant with Standards	Comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Not Applicable	This study does not require a NHS Research Ethics Committee.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
This is a multi-site study undertaking the same research activities; there is therefore one site type. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS, the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and Wales, and the minimum expectations for education, training and experience that PIs should meet (where applicable).
As per the Statement of Activities, a Principal Investigator will be in place at each participating NHS organsation. Support from the NHS participating organisations will be required to identify a lead neonatologist within the participating maternity units to oversee local implementation of the study. GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
It is unlikely that letters of access or honorary research contracts will be applicable, except where external staff employed by another Trust (or University) are involved (and then it is likely that arrangements are already in place). Where arrangements are not already in place, external staff would be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales to aid study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.