Health Research Authority

Dr T Pillay
Clinical Lead Neonatologist
Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton
WV10 0QP

Email: hra.approval@nhs.net

30 March 2017

Dear Dr Pillay

Letter of HRA Approval

Study title:	**OPTIPREM: Optimising neonatal service provision for preterm babies born between 27 and 31 weeks of gestation in England using national data, qualitative research and economic analysis.**
IRAS project ID:	**212034**
Protocol number:	**2016NEO87**
REC reference:	**17/NE/0080**
Sponsor	**The Royal Wolverhampton NHS Trust**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical 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 and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The 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.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

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 Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **212034**. Please quote this on all correspondence.

Yours sincerely

Maeve Ip Groot Bluemink
Assessor

Email: hra.approval@nhs.net

Copy to: *Mrs Sarah Glover, The Royal Wolverhampton NHS Trust – Sponsor & R&D Contact*

Participating NHS organisations in England

Appendix A - List of Documents

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

Document	*Version*	*Date*
Contract/Study Agreement [Optiprem Collaboration Agreement draft 31102016]	1	31 October 2016
Covering letter on headed paper [Covering Letter]	1	03 January 2017
IRAS Application Form [IRAS_Form_01032017]		01 March 2017
Letter from funder		05 December 2016
Letter from sponsor [Sponsor Letter]	1	28 February 2017
Letters of invitation to participant [Letter to Participating units]	1	28 February 2017
Other [additional poster for neonatal unit]	1	04 March 2017
Other [Schedule of Events]	1	24 March 2017
Other [Statement of Activities]	1	24 March 2017
Participant information sheet (PIS) [Participant information sheet/Poster]	4	28 February 2017
Referee's report or other scientific critique report [NIHR Full project description including referees comments and responses]	2	03 January 2017
Research protocol or project proposal [Final Protocol OPTIPREM]	2	03 January 2017
Summary CV for Chief Investigator (CI) [CV chief applicant]	1	27 February 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Project Flow diagram]	2	03 January 2017

Appendix B - Summary of HRA Assessment

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

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations*, *capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Mrs Sarah Glover

Tel: 01902695065

Email: sarah.glover7@nhs.net

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
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	A Statement of Activities has been submitted and it is intended for this to be used as the contract between the Sponsor and NHS sites. Although formal confirmation of capacity and capability is not expected of all or some organisations participating in this study (see *Confirmation of Capacity and Capability* section for full details), and such organisations would therefore be

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			assumed to have confirmed their capacity and capability should they not respond to the contrary, we would ask that these organisations pro-actively engage with the sponsor in order to confirm at as early a date as possible. Confirmation in such cases should be by email to the CI and Sponsor confirming participation based on the relevant Statement of Activities and information within this Appendix B.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	External funding has been secured from the NIHR. There will be no financial provisions to the sites.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No 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	Yes	REC Favourable Opinion was issued by the North East - Tyne & Wear South REC.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments

Section	HRA Assessment Criteria	Compliant with Standards	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

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.

There is one type of participating NHS organisation in England; therefore, there is only one site type.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England 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. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If Chief Investigators, sponsors or Principal Investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the Chief Investigator, sponsor or Principal Investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

The HRA has determined that participating NHS organisations in England participating **are not expected to formally confirm their capacity and capability to host this research,** because **existing data is being provided for research purposes without additional research procedures and without the presence of central research team members on site.**

The HRA has informed the relevant research management offices that you intend to undertake the research at their organisation. However, you should still support and liaise with these organisations as necessary.

- Once the Letter of HRA Approval has been issued the sponsor will be able to commence the study at these organisations when it is ready to do so.

The document "Collaborative working between sponsors and NHS organisations in England for HRA Approval studies, where no formal confirmation of capacity and capability is expected" provides further information for the sponsor and NHS organisations on working with NHS organisations in England where no formal confirmation of capacity and capability is expected, and the processes involved in adding new organisations. Further study specific details are provided in the *Participating*

NHS Organisations and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this appendix.

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 the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Principal Investigator (PI)/Local Collaborator (LC) is not expected for this type of study. GCP training is not a generic training expectation, in line with the HRA 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
The activities at the participating NHS organisation will be undertaken by local staff therefore it is expected that adequate contractual relationship with the host organisation are already in place.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
• The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio. • This application has been submitted for Work Streams 1, 2, 3 & 5 as described in IRAS Form [A13]. Work Stream 4 has not been assessed and does not fall under this initial assessment or subsequent HRA Approval. A new application/Substantial Amendment should be submitted to undertake Work Stream 4. Some activity will take place outside the NHS. HRA approval does not cover activity outside the NHS. Before undertaking activity outside the NHS the research team must follow the procedures and governance arrangements of responsible organisations.