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07 June 2018

Dear Dr Goss

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

Study title:	OPTI-SURF: Optimal surfactant delivery for preterm babies with respiratory distress syndrome. The effect of surfactant dose on outcomes in preterm infants with Respiratory Distress Syndrome
IRAS project ID:	237111
REC reference:	18/WM/0132
Sponsor	Chiesi Limited

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.

*In flight studies' which have already started an SSI (Site Specific Information) application for NHS organisations in Wales will continue to use this route. Until 10 June 2018, applications on either documentation will be accepted in Wales, but after this date all local information packs should be shared with NHS organisations in Wales using the Statement of Activities/Schedule of Events for non-commercial studies and template agreement/ Industry costing template for commercial studies.

Participating NHS organisations in England and Wales **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: **Whale33**). 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 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.

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: Dr Jonathan Loukes

Tel: 07557 215365

Email: j.loukes@chiesi.com

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 **237111**. Please quote this on all correspondence.

Yours sincerely

Michael Pate

Assessor

Email: hra.approval@nhs.net

*Copy to: Dr Jonathan Loukes – Chiesi Limited – Sponsor contact
Donna Johnstone - Leeds Teaching Hospitals NHS Trust – Lead NHS R&D contact.*

List of Documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Contract/Study Agreement template [Funding agreement between Leeds and Chiesi]		06 June 2018
Contract/Study Agreement template [Funding agreement between Imperial and Chiesi]	February 2018	
Contract/Study Agreement template [Grant template for use by sites]		26 April 2018
Copies of advertisement materials for research participants [OPTI-SURF POSTER]	v1.1	05 April 2018
Costing template (commercial projects) [Validated costing template]		10 May 2018
Covering letter on headed paper [Covering letter]		29 March 2018
GP/consultant information sheets or letters [Introduction Letter]	v1.1	18 March 2018
GP/consultant information sheets or letters [Additional Letter]	v1.1	18 March 2018
IRAS Application Form [IRAS_Form_13042018]		13 April 2018
Participant consent form [OPT-OUT FORM]	v1.1	18 March 2018
Participant information sheet (PIS) [OPTI-SURF admission leaflet]	1.4	06 June 2018
Research protocol or project proposal [Protocol]	v2.1	01 February 2018
Response to Request for Further Information		23 May 2018
Summary CV for Chief Investigator (CI) [Dr Kevin Colin William GOSS]		

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	No comments
2.1	Participant information/consent documents and consent process	Yes	Following REC favourable opinion, the admission leaflet was updated via a non-substantial amendment and is now compliant with standards. Sites to note the version number has jumped from v1.2 to v1.4 as v1.3 was not compliant with standards.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	<p>Funding agreements are in place between the sponsor, the lead site and Imperial.</p> <p>Sites will be asked to sign a grant agreement for £2000 to support any additional work required to ensure the quality of the data entered into the database.</p> <p>Although formal confirmation of capacity and capability is not expected of all or some organisations participating in this study, and such organisations would therefore be 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</p>

Section	Assessment Criteria	Compliant with Standards	Comments
			by email to the CI and Sponsor confirming participation based on the relevant Statement of Activities and information within this letter.
4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	A costing template validated by CRN:Yorkshire and the Humber has been provided.
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	No comments
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.

All participating sites are conducting the same activities. Therefore, one site type. A list of participating sites has been provided to the HRA by the sponsor.

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).

Neither a Principal Investigator nor Local Collaborator should be in place at participating sites.

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

No HRCs/LOAs expected as direct care team will only be providing collected data to a REC-approved research database.

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.