Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Health Research Authority

Dr Chris Gale
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Section of Neonatal Medicine
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Email: hra.approval@nhs.net
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20 November 2018

Dear Dr Gale

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

Study title:	**Outcomes following early parenteral nutrition use in very preterm neonates**
IRAS project ID:	**238670**
Protocol number:	**N/A**
REC reference:	**18/NI/0214**
Sponsor	**Imperial College London**

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.

This is a single site study where joint research office arrangements are in place between Sponsor and participating NHS organisation. The R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.

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.

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.

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 **238670**. Please quote this on all correspondence.

Yours sincerely

Isobel Lyle | Senior Assessor
Health Research Authority
T: 0207 972 2496
HRA, Holland Dr, Newcastle upon Tyne NE2 4NQ
Hra.approval@nhs.net or Isobel.lyle@nhs.net
www.hra.nhs.uk

Copy *Mrs Becky Ward, Imperial College London*
Mr Damon Foster, Chelsea and Westminster Hospital NHS Foundation Trust

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]		09 November 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Verification of Insurance]		27 July 2018
GP/consultant information sheets or letters [Letter to participating UKNC units]	1.0	30 July 2018
IRAS Application Form [IRAS_Form_12112018]		12 November 2018
Letter from funder [Funder letter]		20 July 2018
Letter from sponsor [Sponsor Letter]		09 November 2018
Referee's report or other scientific critique report [Certificate of peer review]		20 September 2018
Research protocol or project proposal [Project Protocol]	1.0	20 June 2018
Summary CV for Chief Investigator (CI) [CV for Chief Investigator]		16 April 2018
Summary CV for student [Student CV]		09 November 2018
Summary CV for supervisor (student research) [CV for supervisor: Chris Gale]		16 April 2018
Summary CV for supervisor (student research) [CV for supervisor: Neena Modi]		28 February 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Plain language summary]	1.0	09 November 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	No comments
2.1	Participant information/consent documents and consent process	Not applicable	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and	Yes	This application is a non-commercial single site study taking place in the NHS where that single NHS

Section	Assessment Criteria	Compliant with Standards	Comments
	documented		organisation or Academic associate is the study sponsor, therefore an Agreement is not required.
4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	Financial arrangements will be made locally
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.*

This a non-commercial single site study taking place in the NHS where that single NHS organisation or its Academic associate is also the study sponsor. The single site will facilitate the extract of data from a Database they hold for use in this research project.

If this study is subsequently extended to other NHS organisation(s) in England or Wales, an amendment should be submitted, with a Statement of Activities and Schedule of Events for the newly participating NHS organisation(s) in England or Wales.

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).*

Not applicable. .

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*

Not applicable

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 do not intend to apply for inclusion on the NIHR CRN Portfolio.