HSC Business Services Organisation

Office for Research Ethics Committees Northern Ireland (ORECNI)

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Health and Social Care Research Ethics Committee B (HSC REC B)

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

20 November 2018

Dr Chris Gale
Section of Neonatal Medicine
369, Fulham Road
London
SW10 9NH

Dear Dr Gale

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

The Proportionate Review Sub-committee of the HSC REC B reviewed the above application on 19 November 2018.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a **favourable ethical opinion** of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

The PR Sub-Committee confirmed the study raised no material ethical issues under the following headings:

Social or scientific value; scientific design and conduct of the study

This study is of high scientific value as over 60,000 babies are born prematurely in the UK annually.

The Sub-Committee noted no significant ethical issues with the social or scientific value, scientific design and conduct of the study.

Recruitment arrangements and access to health information, and fair participant selection

The Sub-Committee noted that this is a comparative study of data and, therefore, no participants will be recruited. There will be no changes made to patient management and no additional data will be collected.

The Sub-Committee noted no significant ethical issues.

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)

The Sub-Committee agreed that this is a very low risk study. Data from the National Neonatal Research Database (NNRD) will be extracted by staff from the Neonatal Data Analysis Unit operating within established guidelines.

The Sub-Committee noted no significant ethical issues.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Sub-Committee noted that this is a comparative study of data and, therefore, no significant ethical issues are present.

Informed consent process and the adequacy and completeness of participant information

The Sub-Committee noted that there is no process which requires consent. Therefore, no significant ethical issues arose.

Suitability of the applicant and supporting staff

The Sub-Committee agreed that the research team appears highly experienced and qualified from the CVs provided.

The Sub-Committee noted no significant ethical issues with the suitability of staff to carry out this research study.

Independent review

The Sub-Committee noted that peer reviews are included for this study and present no significant ethical issues.

Suitability of supporting information

The Sub-Committee noted no significant ethical issues.

Other general comments

The Sub-Committee noted no significant ethical issues.

Ethical issues raised, noted and resolved in discussion:

The PR Sub-Committee agreed that this was a well presented study with no material ethical issues.

Approved documents

The documents reviewed and approved were:

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
IRAS Application Form XML file [IRAS_Form_12112018]		12 November 2018
IRAS Checklist XML [Checklist_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

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

There were no declarations of interest declared for this study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

<u>Reporting requirements</u>

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

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 R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

18/NI/0214	**Please quote this number on all correspondence**

Yours sincerely

pp. Melissa Stewart
Professor Patrick Murphy
Chair

Email: PRS@hscni.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers"

Copy to: *Mrs Becky Ward, Imperial College London*
Mr Damon Foster, Chelsea and Westminster Hospital NHS Foundation Trust
HRA.Approval@nhs.net

HSC REC B

Attendance at PRS Sub-Committee of the REC meeting on 19 November 2018

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Elinor Johnston	Research Assistant (Clinical Studies Coordinator)	Yes	
Professor Patrick Murphy	Advisor on Social & Economic Policy	Yes	Chaired Meeting
Mr Leon O'Hagan	Pharmacist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Melissa Stewart	PRS Manager