

Dr Lyvonne Tume
Associate Professor in Child Health
University of West of England
Glenside Campus
Blackberry Hill
Bristol
BS16 1DD

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

09 May 2018

Dear Dr Tume

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

Study title: A Feasibility Study of routine Gastric residual volume measurement in mechanically ventilated Infants and Children: the GASTRIC Study

IRAS project ID: 244006

Protocol number: 1

Sponsor University Hospitals Bristol 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 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 provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a ‘green light’ email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

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 Diane Benton

Email: R&DSponsorship@UH Bristol.nhs.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 **244006**. Please quote this on all correspondence.

Yours sincerely

Thomas Fairman
HRA Assessor

Email: hra.approval@nhs.net

*Copy to: Dr Diane Benton, University Hospitals Bristol NHS Foundation Trust,
(Sponsor Contact and 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> |
|--|----------------|-----------------|
| Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [University Ethical approval] | 1.0 | 18 April 2018 |
| Covering letter on headed paper [cover letter] | 1.0 | 18 April 2018 |
| HRA Schedule of Events | 1.0 | 09 May 2018 |
| HRA Statement of Activities | 1.0 | 09 May 2018 |
| IRAS Application Form [IRAS_Form_18042018] | | 18 April 2018 |
| Letter from funder [NIHR HTA funding letter] | 1.0 | 20 October 2017 |
| Letter from sponsor [Sponsor letter] | 1.0 | 01 March 2018 |
| Participant consent form [GASTRIC Interview_focus group_Healthcare_Professionals_ Consent Form] | 2.0 | 17 April 2018 |
| Participant information sheet (PIS) [GASTRIC Study Staff focus group Information Sheet] | 2.0 | 17 April 2018 |
| Research protocol or project proposal [Study protocol] | 2.0 | 01 March 2018 |
| Summary CV for Chief Investigator (CI) [CH CV] | 1.0 | 18 April 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 | Yes | No comments |
| 3.1 | Protocol assessment | Yes | No comments |
| 4.1 | Allocation of responsibilities and rights are agreed and documented | Yes | <p>The sponsor has submitted the HRA Statement of Activities and intends for this to form the agreement between the sponsor and study sites.</p> <p>The sponsor is not requesting, and does not require any additional contracts with study sites.</p> |
| 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 | <p>No application for external funding has been made.</p> <p>External study funding has been secured from the NIHR HTA. No study funding will be provided to sites, as detailed at Schedule 1 of the Statement</p> |

| Section | Assessment Criteria | Compliant with Standards | Comments |
|---------|--|--------------------------|----------------|
| | | | of Activities. |
| | | | |
| 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 | Not Applicable | 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

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 NHS organisations will undertake the same study activities. There is therefore only one study site 'type' involved in the research.

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 or on 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 the minimum expectations for education, training and experience that PIs should meet (where applicable).

A Principal Investigator should be appointed at study 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

As a non-commercial study undertaken by local staff, it is unlikely that letters of access or honorary research contracts will be applicable, except where local network 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, network staff (or similar) undertaking any of the research activities listed in A18 or A19 of the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance.

For research team members only administering questionnaires or surveys, 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 to aid study set-up.

The applicant has indicated that they do intend to apply for inclusion on the NIHR CRN Portfolio.