

Miss Lucy Li
ENT Registrar
NHS Greater Glasgow and Clyde
1355 Govan Road
Glasgow
G51 4TF

Email: approvals@hra.nhs.uk

10 January 2025

Dear Miss Li

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

Study title:	The TYPHOON Study: Tonsillectomy Postoperative Haemorrhage Outcomes and Observations National Cohort Study
IRAS project ID:	345168
Protocol number:	GN24EN290P
REC reference:	24/NI/0152
Sponsor	NHS Greater Glasgow and Clyde

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.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the “Information to support study set up” section towards the end of this letter.

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 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) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

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 standard conditions 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 **345168**. Please quote this on all correspondence.

Yours sincerely,



Benita Hallewell-Goodwin

Email: approvals@hra.nhs.uk

Copy to: *Mr Adam Wade*

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>
Covering letter on headed paper [REC Cover Letter]		05 November 2024
IRAS Application Form [IRAS_Form_14112024]		14 November 2024
Letter from funder [000448 ENT UK Funding letter]		25 June 2024
Non-validated questionnaire [Tonsillectomy Survey]	1	26 September 2024
Organisation Information Document [Organisation Information Document]	1	14 November 2024
Other [Proportionate Review]	1	18 December 2024
Participant information sheet (PIS) [Participant Information Sheet]	2	26 November 2024
Research protocol or project proposal [Research protocol]	1	29 October 2024
Sample diary card/patient card [Tonsillectomy Excel Data Collection (26 Nov V2)]	2	26 November 2024
Schedule of Events or SoECAT [Schedule of Events]	1	14 November 2024
Summary CV for Chief Investigator (CI) [CV for Lucy Li]	1	19 November 2024
Validated questionnaire [Quality of Life questionnaire]		

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Research activities and procedures as per the protocol and other study documents will take place at participating NHS organisations.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study in accordance with the contracting expectations detailed. Due to the nature of the activities involved, organisations will be expected to provide that confirmation to the sponsor Within 35 days of receipt of the local information pack After	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other agreement to be used with participating NHS organisations of this type.	Study funding arrangements are detailed in the Organisation Information Document	A Principal Investigator should be appointed at participating NHS organisations	Where an external individual will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold a Letter of Access. This should be issued 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).

	<p>HRA/HCRW Approval has been issued. If the organisation is not able to formally confirm capacity and capability within this timeframe, they must inform the sponsor of this and provide a justification. If the sponsor is not satisfied with the justification, then the sponsor may escalate to the National Coordinating Function where the participating NHS organisation is located.</p>				
--	---	--	--	--	--

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.

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