Prof Iain Moppett
Professor of Anaesthesia and Perioperative Medicine /Honorary Consultant
University of Nottingham and Nottingham University Hospitals NHS trust
Anaesthesia and Critical Care
Queen's Medical Centre
Nottingham
NG7 2UH

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

14 February 2024

Dear Prof Moppett

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

Study title:	**Emergency Front of Neck Airway Registry**
IRAS project ID:	**330418**
Protocol number:	**23047**
REC reference:	**24/HRA/0359**
Sponsor	**University of Nottingham**

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 *"After HRA Approval – guidance for sponsors and investigators"* document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, 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 **330418**. Please quote this on all correspondence.

Yours sincerely,

Rachel Katzenellenbogen

Approvals Specialist

List of Documents

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

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		27 June 2023
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Professional Indemnity]		01 August 2023
IRAS Application Form [IRAS_Form_08012024]		08 January 2024
Letters of invitation to participant	Version 1	21 December 2023
Organisation Information Document		
Other [Data protection registration certificate]	Version 1	21 December 2023
Other [Governance Letter]	Version 3	21 December 2023
Research protocol or project proposal [N/A]	Version 1	21 December 2023
Schedule of Events or SoECAT [SoE]		
Summary CV for Chief Investigator (CI) [N/A]	Version 1	21 December 2023
Summary, synopsis or diagram (flowchart) of protocol in non technical language		21 December 2023

IRAS project ID	330418

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	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.	The Chief Investigator may be responsible for all research activities performed at participating NHS organisations.	Where an external individual who does not already hold an NHS employment contract will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold an Honorary Research Contract. External staff holding pre-existing NHS employment contracts should obtain a Letter of Access.

	- After 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.				

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