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Email: approvals@hra.nhs.uk

29 May 2024

Dear Prof Morton

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

Study title:	**CLARITY: An implementation-effectiveness trial of an educational intervention for surgical teams.**
IRAS project ID:	**334172**
Protocol number:	**1**
REC reference:	**24/HRA/2214**
Sponsor	**University of Birmingham**

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 **334172**. Please quote this on all correspondence.

Yours sincerely,
Tina Cavaliere

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Dr Birgit Whitman*

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		20 May 2024
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		1 August 2023
IRAS Application Form [IRAS_Form_28052024]		28 May 2024
Letter from sponsor		16 May 2024
Organisation Information Document	1.5	
Research protocol or project proposal [Protocol]	1.0	07 January 2024
Research protocol or project proposal [CLARITY]	1	07 January 2024
Schedule of Events	1.0	
Summary CV for Chief Investigator (CI) [CLARITY]		13 February 2024

IRAS project ID	334172

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.	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 is conducting only research activities that are limited to access to staff, or staff data (in either identifiable or anonymised form), or anonymised patient data then a Letter of Access is required only if these activities will take place in NHS facilities. 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). These should confirm Occupational Health Clearance. These should confirm standard DBS checks and appropriate barred list checks. Where these activities will not take place in NHS facilities then no arrangements

					under the HR Good Practise Pack are required.

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.