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05 August 2020

Dear Dr Walecka

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

Study title:	**Evaluation of the impact of using anaesthetic machines for ventilation on COVID-19 patients and professionals. A mixed methods study.**
IRAS project ID:	**285642**
REC reference:	**20/HRA/3788**
Sponsor	**Royal Free London 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.

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 **285642**. Please quote this on all correspondence.

Yours sincerely,

Damilola Odunlami

Approvals Specialist

Email: approvals@hra.nhs.uk

List of Documents

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

Document	*Version*	*Date*
Interview schedules or topic guides for participants	1.0	19 June 2020
IRAS Application Form [IRAS_Form_17072020]		17 July 2020
Participant consent form [consent form]	1.1	05 August 2020
Participant information sheet (PIS) [PIS]	1.1	05 August 2020
Research protocol or project proposal [protocol]	1.0	19 June 2020
Summary CV for Chief Investigator (CI) [CI CV]		31 May 2020

IRAS project ID	285642

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
This is a single site study sponsored by the participating NHS organization therefore there is only one site type.	This is a single site study sponsored by the participating NHS organisation. You should work with your sponsor R&D office to make arrangements to set up the study. The sponsor R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.	This is a single site study sponsored by the participating NHS organization therefore no agreements are expected.	External study funding has been secured.	A Principal Investigator should be appointed at study sites.	The sponsor has stated that local staff in participating organisations in England who have a contractual relationship with the organisation will undertake the expected activities. Therefore no honorary research contracts or letters of access are expected for this study.

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 they do not intend to apply for inclusion on the NIHRCRN Portfolio. HRA Approval is granted on the condition that only the retrospective aspect would be undertaken as described in the study protocol "*a retrospective data collection of patients admitted to RFH ITU (and possibly the Barnet Hospital ITU) and connected to anaesthetic machines between the 1st April and 1st June 202*0". You will be required to submit a new application for REC review if you plan on undertaking prospective data collection in the future as described in the study protocol "*a prospective data collection of cases that occur between the 1st June and the 30th October 2020 in order to cover a new period of possible COVID-19 surge*".