Dr Tom Abbott
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Email: approvals@hra.nhs.uk
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03 February 2025

Dear Dr Abbott

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

Study title:	**Analgesia with ibuprofen for patients undergoing elective major Gastro-Intestinal Surgery**
IRAS project ID:	**1011239**
Protocol number:	**1.0**
REC reference:	**24/LO/0885**
Sponsor	**Queen Mary University of London**

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 **1011239**. Please quote this on all correspondence.

Yours sincerely,



Danielle Bromage
Approvals Specialist
Email: approvals@hra.nhs.uk

Copy to: *May Jawad, Queen Mary University of London*

List of Documents

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

Document	*Version*	*Date*
Cover Letter [PROTECT-AEGIS cover letter]	1.0	11 November 2024
Cover Letter [PROTECT-AEGIS CWOW GNA RFI responses Cover letter]	1.0	30 January 2025
GP/consultant information sheets or letters [PROTECT-AEGIS GP Letter]	1.0	11 November 2024
Investigator Brochure/SmPC [Ibuprofen 400 mg solution for infusion SmPC]	n/a	01 March 2023
Investigator Brochure/SmPC [Ibuprofen 400mg Tablet -SmPC]	n/a	04 May 2021
Letter from funder [NIHR Award letter]	n/a	07 July 2023
Letter from sponsor [Sponsorship letter]	4.0	15 November 2024
Non-validated questionnaire [PROTECT-AEGIS NRS pain scale]	1.0	11 November 2024
Non-validated questionnaire [PROTECT-AEGIS OBAS]	1.0	11 November 2024
Organisation Information Document		
Organisation Information Document		
Other [PROTECT-AEGIS mNCA]	n/a	12 November 2024
Participant information and informed consent form [PROTECT Participant Informed EConsent]	1.0	11 November 2024
Participant information and informed consent form [PROTECT-AEGIS Informed Consent Form]	1.0	11 November 2024
Participant information and informed consent form [PROTECT-AEGIS PIS clean]	2.0	20 January 2025
Participant information and informed consent form [PROTECT-AEGIS PIS tracked]	2.0	20 January 2025
Project Information - PDF [ProjectStudyInformation]		31 January 2025
Proof of Insurance [Sponsor's indemnity certificate]	n/a	29 July 2024
Protocol [PROTECT Master protocol clean]	2.0	30 January 2025
Protocol [PROTECT Master protocol tracked]	2.0	30 January 2025
Protocol [PROTECT-AEGIS Appendix 1 clean]	2.0	30 January 2025
Protocol [PROTECT-AEGIS Appendix 1 tracked]	2.0	30 January 2025
Schedule of Events or SoECAT [PROTECT-AEGIS SoECAT]	n/a	12 November 2024
Suitability of the investigator/Investigator CV [Lead Investigator GCP]	n/a	24 March 2023
Suitability of the investigator/Investigator CV [Lead Investigator CV]	n/a	11 November 2024
Suitability of the investigator/Investigator CV [CI CV]	n/a	11 November 2024
Suitability of the investigator/Investigator CV [Chief Investigator GCP]	n/a	11 November 2024

IRAS project ID	1011239

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 but the sponsor is intending to use a separate agreement. The sponsor has supplied the unmodified model agreement and intends to use this with participating NHS organisations.	Study funding arrangements are detailed in the Organisation Information Document	A Principal Investigator should be appointed 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. These should confirm Occupational Health Clearance. These should confirm enhanced DBS checks and appropriate barred list checks.

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.