London - South East Research Ethics Committee
Health Research Authority
2 Redman Place
London
E20 1JQ

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

03 February 2025

Tom Abbott
Queen Mary University of London
Royal London Hospital
London
E1 1FR

Dear Tom Abbott

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

Thank you for your letter of 31 January 2025, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a public registry before the first participant is recruited and no later than six weeks after. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

A 'public registry' means any registry on the WHO list of primary registries or the ICMJE list of registries provided the registry facilitates public access to information about the UK trial.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

Where a deferral is agreed we expect the sponsor to publish a minimal record on a publicly accessible registry. When the deferral period ends, the sponsor should publish the full record on the same registry, to fulfil the condition of the REC favourable opinion.

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

CTIMPs submitted for combined review via IRAS will have study information sent to the ISRCTN registry to facilitate registration unless a deferral has been requested or it has been indicated in the application that the trial is registered, or will be registered, on ClinicalTrials.gov.

The lawful basis for processing your personal data for this purpose is official authority under the NHS Care Act 2014 (for further information please see our privacy notice).

Where the study is registered on ClinicalTrials.gov, please inform deferrals@hra.nhs.uk and the Research Ethics Committee (REC) which issued the final ethical opinion so that our records can be updated.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Where a deferral is agreed, a minimum research summary will still be published in the research summaries database. At the end of the deferral period, we will publish the full research summary.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: Research summaries - Health Research Authority (hra.nhs.uk)

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at Managing your approval - Health Research Authority (hra.nhs.uk)

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

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
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
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

REC Application Form [Ethics]	n/a	31 January 2025
Suitability of the investigator/Investigator CV [Chief Investigator GCP]	n/a	11 November 2024
Suitability of the investigator/Investigator CV [CI CV]	n/a	11 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

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: Quality assurance - Health Research Authority (hra.nhs.uk)

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: Learning - Health Research Authority (hra.nhs.uk)

IRAS project ID: 1011239 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

pp. 

Mr Chris Foy
Chair

Email: londonsoutheast.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for researchers" [SL-AR1]

After ethical review – guidance for sponsors and investigators - **CTIMP Standard Conditions of Approval**

Copy to: May Jawad, Queen Mary University of London

Lead Nation

England: approvals@hra.nhs.uk