Health Research Authority

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

02 September 2025
Dr Tom Abbott
Royal London Hospital
Adult Care Research Office
London E1 1FR

Dear Dr Tom Abbott

Study title:	**Analgesia with ibuprofen for patients undergoing elective major Gastro-Intestinal Surgery**
REC reference:	**24/LO/0885**
Protocol number:	**1.0**
Amendment number:	**Substantial amendment 1**
Amendment date:	**29 July 2025**
IRAS project ID:	**1011239**

Thank you for notifying the Committee of the above substantial amendment to the clinical trial authorisation for this study.

It is noted that authorisation for this amendment is required from the Medicines and Healthcare products Regulatory Agency, but you have not requested an ethical opinion from the Committee.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Amendment Summary [AmendmentSummary]		26 August 2025
Annex 2: Notification of Amendment/Amendment tool [Amendment tool]	1.8	29 July 2025
Cover Letter [PROTECT-AEGIS Cover letter]	n/a	17 July 2025
Investigator Brochure/SmPC [Updated Ibuprofen 400 mg solution for infusion SmPC]	n/a	09 February 2024
Participant information and informed consent form [PROTECT Master PIS tracked]	2.0	19 June 2025
Participant information and informed consent form [PROTECT Master PIS clean]	2.0	19 June 2025
Participant information and informed consent form [PROTECT Master ICF tracked]	2.0	19 June 2025
Participant information and informed consent form [PROTECT	2.0	19 June 2025

Master ICF clean]		
Participant information and informed consent form [PROTECT-AEGIS ICF tracked]	v2.0	19 June 2025
Participant information and informed consent form [PROTECT-AEGIS ICF clean]	2.0	19 June 2025
Participant information and informed consent form [PROTECT and PROTECT-AEGIS eConsent]	v2.0	19 June 2025
Protocol [PROTECT Master protocol tracked]	v3.0	19 June 2025
Protocol [PROTECT Master protocol clean]	v3.0	19 June 2025
Protocol [PROTECT-AEGIS Appendix tracked]	3.0	19 June 2025
Protocol [PROTECT-AEGIS Appendix clean]	3.0	19 June 2025

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.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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

Yours sincerely

Mr Ben Halfon
HRA Approvals Administrator

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