



**Health Research
Authority**

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**

10 February 2025

Dr Tom Abbott
Clinical Senior Lecturer
Queen Mary University of London
Royal London Hospital
Adult Critical Care Research office
London
E1 1FR

Dear Dr Abbott

Study title:	High Flow Nasal Oxygen for patients undergoing elective major abdominal surgery
REC reference:	24/LO/0888
Protocol number:	1.0
IRAS project ID:	350757

Thank you for your letter of 06 February 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.

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 \(hra.nhs.uk\)](#)

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [PROTECT-HFNO Cover letter]	1.0	11 November 2024
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor's insurance certificate]	N/A	29 July 2024
IRAS Application Form [IRAS_Form_18112024]		18 November 2024
Letter from funder [BJA Award letter]	N/A	12 December 2023
Letter from sponsor [PROTECT-HFNO Sponsorship letter]	N/A	14 November 2024
Other [Barts Charity Award letter]	N/A	28 August 2023
Other [CI GCP]	N/A	21 February 2023
Other [PROTECT Master protocol tracked]	2.0	30 January 2025
Other [PROTECT Master protocol clean]	2.0	30 January 2025
Other [PROTECT-HFNO RFI responses cover letter]	1.0	20 January 2025
Participant consent form [PROTECT HFNO Participant Informed Consent Form]	1.0	11 November 2024
Participant consent form [PROTECT Platform Participant Informed EConsent Form]	1.0	11 November 2024
Participant information sheet (PIS) [PROTECT-HFNO Participant Information Sheet]	2.0	20 January 2025
Participant information sheet (PIS) [PROTECT-HFNO PIS - tracked]	2.0	20 January 2025
Protocol [PROTECT-HFNO Appendix - tracked changes]	2.0	20 January 2025
Research protocol or project proposal [PROTECT-HFNO Appendix 2]	2.0	20 January 2025
Summary CV for Chief Investigator (CI) [CI CV]	N/A	11 November 2024

Statement of compliance

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.

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 \(hra.nhs.uk\)](http://hra.nhs.uk/quality-assurance)

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 \(hra.nhs.uk\)](http://hra.nhs.uk/learning)

IRAS project ID: 350757 Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely



Mr Chris Foy
Chair

Email: londonsoutheast.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for
researchers"

Copy to: Dr Mays Jawad

Lead Nation

England: approvals@hra.nhs.uk