NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

Public Consultation on the proposal for National Research Ethics Committee (NREC) application fees

Financial Year 2026

28 October 2025

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Introduction

1.1 National Office

The National Office for Research Ethics Committees (hereafter the 'National Office')[1] was established in 2020 as a business unit within the Health Research Board (HRB), Ireland's leading agency responsible for supporting and funding health research, generating health information and promoting the use of evidence in policy and practice. The HRB supports and enables the operational and strategic work of the National Office team.

The remit of the National Office is to enable and embed a robust, transparent and cohesive research ethics review system that strengthens the national health research infrastructure.

Under the auspices of the Department of Health, the National Office supports National Research Ethics Committees (NRECs) to review the submission of ethics applications and deliver a 'single national ethics opinion' in the following regulated areas of health research:

- clinical trials on medicinal products for human use conducted under the Clinical Trials Regulation (CTR)[2]
- clinical investigations of medical devices conducted under the Medical Devices Regulation (MDR)[3]
- performance studies of in vitro diagnostic medical devices conducted under the In Vitro Diagnostic Regulation (IVDR)[4]

Studies submitted under the CTR are assessed by the NREC for clinical trials (NREC-CT).[5] Studies submitted under the MDR and IVDR are assessed by the NREC for medical devices (NREC-MD).[6]

1.2 Areas of growth

The breadth and complexity of work that the National Office has expanded significantly over the past couple of years. There is a general increase in volume of applications, for both new and substantial modifications, which has resulted in more complex and consistent interaction with the CTIS to ensure applications are managed rigorously and in alignment with other EU Member States, whilst meeting EU timelines.

The work of the National Office in supporting Ireland's position at an EU level has also grown considerably and now core to the remit of the office. Our participation as a representative EU member state on MedEthicsEU, the CTR Collaborate initiative and the COMBINE

[1] National Office for Research Ethics Committees
[2] REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use
[3] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices
[4] REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices
[5] https://www.nrecoffice.ie/committees/nrec-ct/
[6] https://www.nrecoffice.ie/committees/nrec-md/

Programme is helping to shape and inform the harmonised implementation of the EU Regulations.

The National Office is making significant efforts to engage further with both non-commercial and commercial sponsors, to provide pre-submission advice in advance of applying to the National Research Ethics Committees. We see a positive trend to an increase in non-commercial studies being carried out in Ireland.

We further wish to expand our support for and engagement with our patient and public involvement NREC members.

Please see the National Office Annual Report 2024[7]

1.3 Application & fee process in Ireland

1.3.1 Applications under the MDR and IVDR

Applications that fall under the MDR and IVDR require a separate review by the HPRA and by the NREC-MD.

To apply, sponsors must pay the relevant fee in advance of submission to the NREC-MD. The process of payment is facilitated through advanced invoice and is outlined in detail on our website: https://www.nrecoffice.ie/apply-2/fees/

1.3.2 Applications under the CTR

Sponsors conducting a clinical trial in Ireland under the CTR, must apply for approvals by submitting the relevant application dossier via the single EU portal, Clinical Trials Information System (CTIS).[8]

There are two elements to the assessment process that inform the application fee structure:

	Dossier	Assessed by
Part I	e.g. protocol, investigator's brochure, investigational medical product dossier, etc	HPRA and NRECs - joint national assessment
Part II	e.g. participant information leaflets, consent documents, suitability of the investigator and clinical sites, etc	NRECs - ethics assessment

A fee is charged by Ireland, where the fee is paid to and processed by the HPRA and on behalf of the National Office in accordance with our financial procedures.

The Sponsor will pay the total fee to the HPRA at the time of submitting the initial (i.e. new studies) clinical trial dossier (Part I and Part II together, Part I only, subsequent Part II) to the

[7] Annual Report 2024

[8] Clinical Trials Information System

CTIS. Following validation, the HPRA will transfer the corresponding fee portion to the National Office.

Similarly for substantial modifications to Part I and II, Part I only, or Part II only documents, the fee will be paid to HPRA, and the relevant portion transferred to the National Office in accordance with our financial procedures.

No refund will be permitted once the application is validated.

The process of payment is outlined in detail on the HPRA website: http://www.hpra.ie/homepage/medicines/regulatory-information/medicines-fees

1.4 Review of fees

The National Office is committed to ensuring the business of the NRECs is managed with efficiency and rigor, in accordance with legislative obligations and driven by a high performing team and operational excellence.

It is a priority for the National Office and NRECs that the national ethics review system is efficient, predictable and sustainable. Preparedness for current and future work volumes is core to ensuring we can deliver on this remit.

In line with that commitment, a review of fees has been carried out by the National Office. In the spirit of transparency, this consultation document provides details of the fees intended to be charged for all ethics applications submitted to the respective NRECs for consideration, in 2026.

The proposed changes to the fees for ethics applications submitted under the respective EU Regulations are summarised in the **Tables in Appendix I.**

In brief:

- There is a proposed increase to all application fees by 10% in line with inflation and additional operational costs.
- There is a proposed increase in fees for ethics applications for substantial modifications submitted under the IVDR and MDR, to align with fees under the CTR.
- There is a proposed increase in the appeals application fee to reflect the level of work that would be required by the National Office to support a robust and efficient appeals process.

NOTE: There is no change to the 'No-fee payment' for non-commercial sponsors,[9] reflecting our continued commitment to support non-commercial sponsors conducting research under the EU Regulations.

[9] Where the sponsor is academic/ not-for-profit funded, non-commercial fees apply

1.5 Public consultation process

In the first year of operations, the public consultation on fees for 2021 was a jointly coordinated initiative between the national competent authority, the Health Products Regulatory Authority (HPRA) and the National Office and focused solely on the fees for applications submitted under the CTR.

Since that time the National Office has carried out a public consultation independent of the HPRA to better align with fee payment structures for ethics assessments with European counterparts and to better reflect the service provided by the NRECs in the assessment of regulated research studies.

In 2024 and 2025 there were no changes to the application fee structure.

The public consultation for the financial year 2026 is seeking feedback on the proposed new fee changes for applications submitted under the EU Regulations.

Proposed changes to the fees for applications to the Health Products Regulatory Authority (HPRA) for 2026, can be viewed on the HPRA website.

The National Office invites stakeholders to share their views with us on the proposal below.

Contributions to the consultation on these proposals should be submitted to the National Office by 7 November 2025. Contributions should be sent by email to nationaloffice@nrec.ie with subject “NREC Fees consultation”.

1.6 Proposed fees

1.6.1 General increase in application fees

The National Office has not increased its fees since 2023 and now proposes an increase in all fees by 10% for applications submitted under the CTR, MDR and IVDR.

The rational for this increase is to reflect the growth in operational requirements for the National Office.

1.6.2 Increase application fees for submissions under the MDR and IVDR

In addition to overall increase of 10%, it is proposed to increase the fee for substantial modification applications submitted under the MDR and IVDR to bring them in line with the application fees for submission under the CTR. The increase in fees reflects the parity of service provided by NRECs and the National Office for all submissions under the EU Regulations.

1.6.3 Increase in the Appeals application fee

The National Office is proposing to increase the Appeals application fee to reflect the level of resourcing, operational support and additional ethics expertise required to ensure a robust appeals process can be delivered expediently, when required.

1.7 Contact details

The National Office welcomes comments on these proposals and invites respondents to comment.

Contributions to the consultation on these proposals may be provided to the National Office by 12pm, 10 November 2025. Contributions should be sent by email to nationaloffice@nrec.ie with subject “NREC fees consultation”.

Appendix I. Proposed national fees under the CTR, MDR and IVDR

Table 1. Proposed fees for applications submitted under the Clinical Trials Regulation (for commercial sponsors only)

Clinical Trials on Investigational Medicinal Products (IMP)		Current fees	Proposed fee new/change	Total percentage increase
New/Initial application	Reporting Member State (RMS) *(Part I & II, Part I only)*	€2,000	€2200	10%
	Member State Concerned (MSC) (Part I & II, Part I only)	€1,500	€1650	10%
	Mono national *(Part I & II, Part I only)*	€1,500	€1650	10%
	Supplement – where Ireland subsequently becomes the Reporting member state for Mono national trial	€500	€550	10%
	RMS -2nd & subsequent waves	€400[10]	€440	10%
Substantial modification application *(RMS, MSC)*		€400[11]	€440	10%
Appeals application for the decision of the NREC-CT		€1,200	€2,000	67%
Pre-submission consultation advice service for applications		No charge	No charge	-

[10] Amended 31/10/2025, corrected amount from €500 / €550 to €400 / €440 due to a clerical error

[11] Amended 03/11/2025, corrected amount from €500 / €550 to €400 / €440 due to a clerical error

Table 2. Proposed fees for clinical investigations submitted under the Medical Devices Regulation (for commercial sponsors only)

Clinical investigation of medical devices	Current fees	Proposed fee change	Total percentage increase
New clinical investigation application	€1,500	€1,650	10%
Substantial modification application	€300	€440[12]	68% (in line with CTR fees)
Appeals application	€1,200	€2,000	67%
Pre-submission consultation service	No charge	No charge	-

Table 3. Proposed fees for performance studies submitted under the In Vitro Diagnostics Regulation (for commercial sponsors only)

Performance studies of in vitro diagnostic devices	Current fees	Proposed fee change	Total percentage increase
New performance study application	€1,500	€1,650	10%
Substantial modification application	€300	€440[13]	68% (in line with CTR fees)
Appeals application	€1,200	€2,000	67%
Pre-submission consultation service	No charge	No charge	-

[12] Amended 03/11/2025, corrected amount from €500 / €550 to €400 / €440 due to a clerical error

[13] Amended 03/11/2025, corrected amount from €500 / €550 to €400 / €440 due to a clerical error