NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

Public Consultation on proposal for NREC Fees for 2026 - Outcomes report

November 2025

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1. Overview - public consultation process

The National Office for Research Ethics Committees (hereinafter 'National Office' held a public consultation on proposed fees for 2026[1] for all ethics applications submitted to the National Research Ethics Committees (NRECs) for health research regulated under the Clinical Trial Regulations (CTR), Medical Device Regulations (MDR), and *In Vitro* Diagnostic Regulations (IVDR).

The National Office invited stakeholders to share their views on the proposal fee structure. Contributions to the consultation on these proposals were submitted to the National Office by the closing date of 10 November 2025.

This process was run similarly to the public consultation carried out by the Health Products Regulatory Authority[2], which has now published its outcome.[3]

The National Office is grateful for contributions submitted to it, which are summarised in this report.

2. Summary of submissions received

The National Office received one response to the consultation, from an industry representative group. The following feedback was provided by the respondent:

- The Respondent acknowledged the National Office's commitment to maintaining a robust framework and appreciated the transparency of the consultation process.
- Concern was expressed regarding the proposed 10% increase in NREC fees for 2026 as the cost of conducting Clinical Trials is already substantial and further increased fees risk undermining Ireland's attractiveness as a destination for clinical research and pharmaceutical innovation since additional financial burdens could deter sponsors from initiating trials locally.

3. National Office response to the submissions

The National Office has carefully reflected on the feedback provided by the Respondent. The National Office considers the increases extremely modest and reflective of the service and support that the NRECs and National Office provides and wishes to build on over the next year.

No core fee is being increased more than €200, with the exception of the appeal fee, which is considered to be appropriate given additional work that would be involved to operationalise an appeal.

The National Office does not consider the additional increased fee range of €40-€200 to be significant for any one application and should not financially impact any commercial sponsor. Nor should this modest increase be a deterrent to any Sponsor wishing to conduct a regulated study in Ireland, when taking into account the NRECs, with the support of the National Office, deliver robust national ethics opinions whilst meeting the EU legislative timelines.

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

[2] Annual Review and Proposal for Fees – Financial Year 2026 Human Medicines, Compliance Activities, Blood, Tissue Establishments and Organs and Medical Devices

[3] Outcome of the Process - Public Consultation on proposed fees for Human Medicines, Compliance, Medical Devices and Veterinary Medicines for 2026

Furthermore, the National Office endeavours to support all sponsors in navigating the national ethics review process, complexity of the EU Regulations, including the requirements under the Clinical Trials Information System.

The National Office remains of the view that the fee increases are justified to reflect the persistent and complex workload that the National Office manages and the NREC members are required to undertake.

The National Office gratefully acknowledges and has carefully considered the Respondents points raised.

4. Conclusion

The National Office remains committed to embedding a robust, sustainable and trusted national research ethics committee system in Ireland, including meeting its regulatory requirements under the various legislative frameworks. It's primary objective it to ensure this national ethics review system has the safety, dignity and well-being of research participants at the fore of the ethics opinions delivered.

To continue to drive these key objectives, it is critical for the National Office to reflect on all aspects of its operations and its strategic objectives, including the current suitability of the fees on balance with the workload experienced by the National Office and its Committee members.

As the National Office and NRECs continue to operate under the respective Regulations into 2026, we will commit to review the fees to determine if they are fit for purpose and commensurate with the application submissions and subsequent ethics assessments experienced. We will carry out this process in line with the HPRAs public consultation process as appropriate.

The National Office is committed to continuous and ongoing improvements of its processes, while ensuring full compliance with the Regulations.

The fee structure as outlined in the original consultation and set out in Appendix I of this report will be submitted to the Department of Health.

We wish to thank the respondent that contributed to the consultation process.

The National Office for Research Ethics Committees

21 November 2022

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 2025	New fees 2026	Total percentage increase
New/Initial application	Reporting Member State (RMS) *(Part I & II, Part I only)*	€2,000	€2,200	10%
	Member State Concerned (MSC) (Part I & II, Part I only)	€1,500	€1,650	10%
	Mono national *(Part I & II, Part I only)*	€1,500	€1,650	10%
	Supplement – where Ireland subsequently becomes the Reporting Member State for Mono national trial	€500	€550	10%
	RMS - 2nd & subsequent waves	€400	€440	10%
Substantial modification application *(RMS, MSC)*		€400	€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	-

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

Clinical investigation of medical devices	Current fees 2025	New fees 2026	Total percentage increase
New clinical investigation application	€1,500	€1,650	10%
Substantial modification application	€300	€440	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 2025	New fees 2026	Total percentage increase
New performance study application	€1,500	€1,650	10%
Substantial modification application	€300	€440	68% (in line with CTR fees)
Appeals application	€1,200	€2,000	67%
Pre-submission consultation service	No charge	No charge	-