

Public Consultation on proposal for NREC Fees - Outcomes report

November 2022

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1. Overview - public consultation process

The National Office held a public consultation on proposed fees for 2023¹ for all ethics applications submitted to the National Research Ethics Committees (NRECs) for health research regulated under the Clinical Trial Directive (CTD), 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 28th October 2022.

This process was run in parallel with the public consultation carried out by the Health Products Regulatory Authority.²

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 considered that the proposed increase in fees would compromise Ireland's ability to offer a competitive environment to carry out clinical trials, specifically in terms cost, adherence to timelines and predictability compared to other member states.
- Specifically, the proposed increase in the fees for substantial amendment applications was raised as a concern as the respondent's view was that timelines to validation and approval (for CTD studies) were slow.
- Although not part of the public consultation, the respondent further noted that evidence of fee payment in advance of submission to the National Office Ireland is not in line with some EU Member States. The respondent has requested the National Office to consider revising its processes such that Sponsors are not required to provide evidence of payment in advance as a means to expedite the application submission process, and improve the potential for competitiveness of clinical trials in Ireland.

3. National Office response to the submissions

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

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

Notwithstanding the unanticipated complexity and workload that has been experienced through submissions under the CTD, CTR, MDR and IVDR, the pace at which ethics opinions are now delivered has improved and within legislative timelines.

¹ https://www.nrecoffice.ie/wp-content/uploads/NREC-fees-2023-Public_Consultation-Final.pdf

² <https://www.hpra.ie/docs/default-source/default-document-library/public-consultation-on-human-medicines-medical-device-and-compliance-fees-2023.pdf?sfvrsn=2>

The increase in the application fees will be a critical to enable the National Office and NRECs to leverage this financial support to build and strengthen capacity expertise within the National Office team and NREC review system more broadly.

Even when readjusted, it is considered that the fees are competitive with fees across other EU Member States and would not reasonably be the sole driver of clinical trials not being conducted in Ireland, given the overall significant cost of running trials.

In terms of the payment process and requirement for proof of payment upon submission, at this time the National Office will not revise its process, which is aligned with the payment process of the Health Products Regulatory Authority³.

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, including the current suitability of the fees on balance with the workload experienced by the National Office and its volunteer Committee members.

As the National Office and NRECs continue to operate under the respective Regulations in practice into 2023, we will commit to review the fees to see if they are fit for purpose and commensurate with the application submissions and subsequent ethics assessments experienced. The review will be carried out in Q3 2023 and as result of that, review fees may be increased or decreased. This review will be transparent and subject to a public consultation. Separately, 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

16 November 2022

³ <https://www.hpra.ie/docs/default-source/default-document-library/payment-fees-instructions.pdf?sfvrsn=2>

Appendix I. NREC FEES for 2023

Table 1. NREC-MD fees

New Clinical Investigations and Performance Studies		2023 fees
Commercial		€1,500
Non-Commercial		€150
Fee for Each Site Related to a New Application		
Commercial		-
Non-Commercial		€0
Substantial Modifications of Clinical Investigations and Performance Studies		
Commercial		€300
Non-Commercial		€50
Appeal of NREC-MD Decision		
Commercial		€1,200
Non-Commercial		€100

Table 2. NREC-CT fees under CTD

New Clinical Trials of Investigational Medicinal Products	2023 fees
Commercial	€1,500
Non-Commercial	€150
Fee for Each Site Related to a New Application	
Commercial	-
Non-Commercial	-
Substantial Modifications of Clinical Trials of Investigational Medicinal Products	
Commercial	€400
Non-Commercial	€50

Table 3. NREC-CT fees under CTR

New Clinical Trials of Investigational Medicinal Products	2023 fees
Mono national/ Member state concerned (MSC)	€1,500
Reporting member state (RMS)	€2,000
Supplement – where Ireland subsequently becomes the Reporting member state for Mono national trial	€500
Reporting member state – 2nd & subsequent waves	€500
Non-commercial	€150
Substantial Modifications of Clinical Trials of Investigational Medicinal Products	
Mono national/ Reporting member state/ Member state concerned	€400
Non-commercial	€50
Appeal of NREC-CT Decision	
Commercial	€1,200
Non-commercial	€100

Table 4. NREC-CT fees under CTR combined with the HPRA fees

New clinical trial (CT) applications	2023 HPRA Fees		2023 NREC Fees		Total Fees	
	CT with IMPD	CT with no IMPD or with simplified IMPD or a low intervention trial	CT with IMPD	CT with no IMPD or with simplified IMPD or a low intervention trial	CT with IMPD	CT with no IMPD or with simplified IMPD or a low intervention trial
Mono national	€1,920	€905	€1,500	€1,500	€3,420	€2,405
Reporting member state (RMS)	€6,700	€5,500	€2,000	€2,000	€8,700	€7,500
Member state concerned (MSC)	€1,700	€635	€1,500	€1,500	€3,200	€2,135
Supplement – where Ireland subsequently becomes the reporting member state for mono national trial	€4,780	€4,595	€500	€500	€5,280	€5,095
Reporting member state – 2 nd & subsequent waves	€500	€500	€500	€500	€1,000	€1,000
Non-commercial	€150	€150	€150	€150	€300	€300

Clinical trial substantial modifications (SM)	2023 HPRA Fees		2023 NREC Fees		Total Fees	
	SM with the addition of new IMPD	SM other	SM with the addition of a new IMPD	SM other	SM with the addition of a new IMPD	SM other
Proposed fees (Part I only or Parts I & II)						
Mono national	€980	€510	€400	€400	€1,380	€910
Reporting member state (RMS)	€1200	€810	€400	€400	€1,600	€1,210
Member state concerned (MSC)	€925	€430	€400	€400	€1,325	€830
SM non-commercial	€50	€50	€50	€50	€100	€100
Proposed fees (Part II only)						
Commercial	-	-	€400	€400	€400	€400
Non-commercial	-	-	€50	€50	€50	€50