

National Office for Research Ethics Committees – Payment of Fees

Applicant procedure for payment of fees for ethics review by
National Research Ethics Committees

Version 3

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1 Definitions

EFT: Electronic Fund Transfer

HRB: Health Research Board

NREC: National Research Ethics Committee

NREC-CT: National Research Ethics Committee for Clinical Trials of Investigational Medicinal Products

NREC-MD: National Research Ethics Committee for Clinical Investigations of Medical Devices and Performance Studies for *In Vitro* Diagnostics

PI: Principal Investigator

2 Payment of fees

- i) For applications submitted under the Clinical Trials Regulations (EU 536/2014), fees for submissions¹ are to be paid via the Clinical Trials Information System (CTIS). The payment of these submissions does not follow the process of having an invoice being raised outlined below. Please see a link to the Clinical Trials Information System (CTIS) portal here: <https://euclinicaltrials.eu/ctis-for-sponsors/>
- ii) For applications submitted under the Clinical Trials Directive² (EC No. 2001/20/EC), Medical Devices Regulation (EU 2017/745)³ and In Vitro Diagnostic Medical Devices Regulations (EU 2017/746)⁴, applicants must pay the relevant fee in advance of submission to the National Office for Research Ethics Committees. An applicant should complete the Payment Processing Form available on our website. The completed Payment Processing Form must be e-mailed to nrec-finance@nrec.ie, with the reference “NREC-Payment Processing Form” followed by the PI/sponsor name. An invoice will then be sent to the applicant with bank payment information.
- iii) All payments must be made in full, in Euro, and paid by credit transfer / EFT, with the invoice number referenced on the transaction.
- iv) Please obtain a Bank Advice Note for your transaction. This should include all details listed below:
 - Invoice reference number
 - Beneficiary IBAN
 - Date of payment

¹ Set out in Irish law under S.I. 679 of 2022 at <https://www.irishstatutebook.ie/eli/2022/si/679/made/en/pdf>

² Set out in Irish law under S.I. 727 of 2022 at <https://www.irishstatutebook.ie/eli/2022/si/727/made/en/pdf>

³ Set out in Irish law under S.I. 726 of 2022 at <https://www.irishstatutebook.ie/eli/2022/si/726/made/en/pdf>

⁴ Set out in Irish law under S.I. 725 of 2022 at <https://www.irishstatutebook.ie/eli/2022/si/725/made/en/pdf>

Should any of these details be omitted, the processing of the application may be delayed.

Should issues arise in the payment of fees, please contact the National Office finance team at nrec-finance@nrec.ie.

3 Fees

3.1 NREC-MD fees for applications submitted under the Medical Devices Regulation (EU 2017/745) and *In Vitro* Diagnostic Medical Devices Regulations (EU 2017/746).

NREC-MD fees	Commercial ⁵	Non-Commercial ⁶
New Clinical Investigations and Performance Studies ⁷	€1,500	€150
Substantial Modifications of Clinical Investigations and Performance Studies	€300	€50
Appeal of NREC-MD Decision	€1,200	€100

3.2 NREC-CT fees for applications submitted under the Clinical Trials Directive (EC No. 2001/20/EC).

NREC-CT fees	Commercial ⁵	Non-Commercial ⁶
New Clinical Trials of Investigational Medicinal Products	€1,500	€150
Substantial Modifications of Clinical Trials of Investigational Medicinal Products	€400	€50

⁵ Where the study is industry funded or sponsored, commercial fees apply

⁶ Where the sponsor is academic/ not-for-profit funded, non-commercial fees apply

⁷ This includes Post-Market Clinical Follow-Up Studies for Medical Devices

3.3 NREC-CT fees for applications submitted under the Clinical Trials Regulation (EU 536/2014).

NREC-CT fees for applications submitted under the Clinical Trials Regulation (EU 536/2014)	Commercial⁵	Non-Commercial⁶
New Clinical Trials of Investigational Medicinal Products		
Mono national/ Member state concerned (MSC)	€1,500	€150
Reporting member state (RMS)	€2,000	€150
Supplement – where Ireland subsequently becomes the Reporting member state for Mono national trial	€500	€150
Reporting member state – 2nd & subsequent waves	€500	€150
Substantial Modifications of Clinical Trials of Investigational Medicinal Products		
Mono national/ Reporting member state/ Member state concerned	€400	€50
Appeal of NREC-CT Decision		
Appeal of NREC-CT Decision	€1,200	€100

4 Application submission

Applicants should include the related bank advice note when submitting their documentation to the relevant NREC for review.

This will serve as evidence of payment and will support the validation of an application.

Evidence of payment is an essential component of application validation, and applicants should allow sufficient time for processing of their application fees in advance of the submission cut-off dates.