National Office for Research Ethics Committees – Payment of Fees

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

Version 4

Title:	National Research Ethics Committees Payment of Fees Procedure
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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 submissions[1] 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 Directive[2] (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.

iii) An applicant should complete the Payment Processing Form available on our website, to 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.

iv) All payments must be made in full, in Euro, and paid by credit transfer / EFT, with the invoice number referenced on the transaction.

v) Please obtain a Bank Advice Note for your transaction. This should include all details listed below:

- Invoice reference number
- Beneficiary IBAN

[1] Set out in Irish law under S.I. 697 of 2023 at https://www.irishstatutebook.ie/eli/2023/si/697/made/en/pdf

[2] Non-commercial fees shall no longer apply to substantial modification applications submitted under the Clinical Trial Directive, as of 1st January 2024. S.I. to be confirmed.

[3] Set out in Irish law under S.I. 671 of 2023 at https://www.irishstatutebook.ie/eli/2023/si/671/made/en/pdf

[4] Set out in Irish law under S.I. 670 of 2023 at https://www.irishstatutebook.ie/eli/2023/si/670/made/en/pdf

- Date of payment

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	No charge
Substantial Modifications of Clinical Investigations and Performance Studies	€300	No charge
Appeal of NREC-MD Decision	€1,200	No charge

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]
Substantial Modifications of Clinical Trials of Investigational Medicinal Products	€400	No charge

[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 have been removed
[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)	Commercial[5]	Non-Commercial[6]
New Clinical Trials of Investigational Medicinal Products		
Mono national/ Member state concerned (MSC)	€1,500	No charge
Reporting member state (RMS)	€2,000	No charge
Supplement – where Ireland subsequently becomes the Reporting member state for Mono national trial	€500	No charge
Reporting member state – 2nd & subsequent waves	€500	No charge
Substantial Modifications of Clinical Trials of Investigational Medicinal Products		
Mono national/ Reporting member state/ Member state concerned	€400	No charge
Appeal of NREC-CT Decision		
Appeal of NREC-CT Decision	€1,200	No charge

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.