

## Appeals Policy

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### National Research Ethics Committee(s)

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#### 1. Definitions

The following terms have the meaning assigned to them by the applicable national legislation:

- Appellant
- Health Products Regularity Authority (“the Authority”)
- National Office
- National Research Ethics Committee (“National REC”)
- Opinion

#### 2. Purpose

- 2.1. The purpose of this policy is to outline the process for Applicants/Sponsors for appealing an ‘unfavourable’ opinion which has been made by a National Research Ethics Committee (NREC), following its assessment of an application submitted for ethics review.
- 2.2. This policy aligns with the requirements of, and is in compliance with, the applicable national legislation for the specified NREC (see Table 1).
- 2.3. This policy has been designed to adhere to the principles of proportionality, fairness, consistency and transparency.

#### 3. Scope

##### 3.1. In scope

- 3.1.1. The National Research Ethics Committees (NRECs) are authorised under national legislation to complete an ethical assessment of, and give a single national opinion on, studies conducted under specified articles of the applicable EU Regulations (see Table 1).
- 3.1.2. This policy applies to appellants engaged in one or more specified study types, which has received an “unfavourable” opinion following ethics assessment by the applicable NREC.

#### Table 1: Applicable National Legislation and EU Regulations

Study Type	National Legislation	EU Regulation
Clinical Trial of an Investigational Medicinal Product	S.I. 41/2022 <sup>1</sup>	Clinical Trial Regulation: Regulation (EU) No 536/2014
Clinical Investigation of a Medical Device	S.I. 671/2023 <sup>2</sup>	Medical Device Regulation: Regulation (EU) No 2017/745
Performance Study of an In Vitro Diagnostic Medical Device	S.I. 257/2022 <sup>3</sup>	In Vitro Diagnostic Medical Device Regulation: Regulation (EU) No 2017/746

#### 4. Appeals procedure

- 4.1. When ethics assessment of a study results in an 'unfavourable' opinion from a National Research Ethics Committee (NREC), an appellant may submit an appeal to the National Office for National Research Ethics Committees (National Office).
- 4.2. The notice of appeal shall be no later than 30 days from the date of issuance of the decision of the NREC to the appellant.
- 4.3. Prior to submitting a formal appeal to an NREC appeal panel, applicants are encouraged to contact the National Office to seek clarifications on the decision or to discuss next steps for resubmission of the application. The National Office may be able to provide information to address queries which may be pertinent to the decision to proceed with a formal appeal. Please note that an 'unfavourable' opinion will not be overturned at this stage.
- 4.4. A suitable appellant on behalf of the study (generally understood to be the individual identified as the lead contact for the study) should notify the National Office in alignment with timelines as documented in the applicable national legislation. If the appeal deadline expires on a Saturday, Sunday or public holiday, it will be extended to the following business day (until such time as the legislation specifies these timelines in working/calendar days).
- 4.5. A formal appeal should be submitted electronically to the generic email address of the applicable NREC which is provided on the website of the National Office.

<sup>1</sup> <https://www.irishstatutebook.ie/eli/2022/si/41/made/en/pdf>

<sup>2</sup> <https://www.irishstatutebook.ie/eli/2023/si/671/made/en/print>

<sup>3</sup> <https://www.irishstatutebook.ie/eli/2022/si/257/made/en/pdf>

4.6. The appellant should include:

- a. A cover letter which formally requests an appeal of an NREC decision, and which includes the below details:
  - Applicable NREC application ID and/or EU level identification codes, such as the European Union Drug Regulating Authorities Clinical Trials Database (EudraCT) code, Clinical Investigation ID (CIV-ID).
  - The title of the study, the name and address of the Sponsor, the name and address of the Sponsor's legal representative in the EU, and the name and site address of the national Principal Investigator.
  - A statement setting out in detail the grounds for the appeal.
  - A statement setting out if the national competent authority has been notified of the appeal being requested.
- b. A copy of the decision letter from the NREC which is the subject of the appeal.
- c. A copy of the application to the NREC, including initial submission and response to request for further information comments, as applicable.
- d. Evidence of payment of fees, as set out in the National Office fee schedule<sup>4</sup>.
- e. Any documentary evidence which the appellant wishes to submit in support of the appeal.

4.7. The National Office shall acknowledge receipt of the formal appeal and, once set, provide a date for the appeal hearing, and inform the appellant accordingly. The NREC(s) shall route and manage requests for appeal with all reasonable expedition.

4.8. The National Office shall form an appeal panel as per the applicable national legislation, drawn from existing NREC members and/or external experts or PPI members as deemed necessary/appropriate, and with due consideration being given to the subject area of the study under assessment. Members of the appeal panel are bound by the same principles of confidentiality and disclosure of interests as members of the NRECs.

4.9. The appeal panel shall

- 4.9.1. Consist of not less than 7 and not more than 11 members each of whom, in the opinion of the Head of the National Office having regard to the functions of the appeal panel, is suitably qualified to hear the appeal.
- 4.9.2. The Head of the National Office shall appoint one of the members of the appeal panel to be its chairperson.
- 4.9.3. None of the members appointed to an appeal panel shall be a member of the National REC that was involved in considering the application which is the subject of the appeal.

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<sup>4</sup> <https://www.nrecoffice.ie/apply/fees/>

- 4.9.4. An appeal panel shall determine its own procedures and will generally follow the same operational and consensus-based decision-making procedures as the NRECs.
- 4.10. The appeal panel shall be supported administratively and operationally by the National Office, which shall collate and make available all previously submitted information which relates to the initial application(s) for ethics review of the applicable study.
- 4.11. The appeal panel shall review the appeal and reach an opinion as per the applicable national legislation, which grants the appeal panel the authority to revoke or uphold the NREC opinion which is the subject of the appeal.
- 4.12. The appellant shall provide, if applicable, such additional written information (including any documentation) that the appeal panel requests within the period specified by the appeal panel.
- 4.13. The appeal panel may invite submissions from any person whom it considers appropriate and may consult any person whom it believes could assist with the review of the appeal.
- 4.14. Having considered an appeal, the appeal panel shall either confirm the decision issued by the NREC or allow the appeal and notify the National Office as soon as practical.
- 4.15. Both the appellant and the Chairperson of the previously reviewing National Research Ethics Committee involved shall be notified of the result in writing.
- 4.16. The National Office shall ensure that obligations to partner organisations (including the national regulatory body/competent authority) are met, which includes notifying them of the submission of the appeal by the appellant, and its outcome.
- 4.17. The appeal panel shall be dissolved, and cease activities, as per the applicable national legislation.

## 5. Additional Information

- 5.1. Any questions about this policy should be referred to the National Office:  
nationaloffice@nrec.ie

Version Control Sheet (VCS)

<b>Policy Title</b>	NREC Appeals Policy
<b>Policy Owner and Title</b>	Emily Vereker, Head of Office
<b>Business Area:</b>	National Office for Research Ethics Committees
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Is this policy to be published on the National Office website?      Yes

Reason for publication:

- Information for stakeholders
- Requirement under legislation

<b>Version</b>	<b>Date</b>	<b>Author</b>	<b>Rationale</b>	<b>Approved</b>
V1	April 2024	Lucia Prihodova	Legislative requirement to implement a policy for the management of appeals to unfavourable opinions of an NREC.	Approved