

## National Office for Research Ethics Committees

### Complaints Policy & Procedures

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#### 1. Background

The National Office for Research Ethics Committees (the 'National Office') endeavours to carry out its role with professionalism and courtesy and to the highest quality.

The National Research Ethics Committees ('Committees') are committed to delivering robust national research ethics opinions to support researchers to conduct research to the highest standards of ethics, ensuring the safety, dignity and wellbeing of research participants. The National Office team are responsible for supporting the Committees in this role.

We acknowledge that matters may arise in relation to the work of the National Office and Committees, and we encourage feedback from our stakeholders to help us improve and address any concerns promptly.

We are responsible for managing any concerns and complaints, if and when they arise and which are deemed valid to the work we do. The National Office will make every effort to coordinate all complaints and assist all Complainants, as fairly as possible.

As the National Office is a business unit within the Health Research Board (HRB), this policy also aligns with the HRBs Customer Service Charter.<sup>1</sup>

#### 2. Purpose of Policy

This policy sets out the National Office policy and procedures for:

- 2.1. Complaints about the ethical conduct of a person carrying out a study approved by any committee under the remit of the National Office (hereinafter 'Committee(s)'), namely:
  - a. National Research Ethics Committees for clinical trials for medicinal products (NREC-CTs),
  - b. National Research Ethics Committees for clinical investigations for medical devices and performance studies for *in vitro* diagnostic devices (NREC-MD),
  - c. any other committee under the National Office's remit, at the time of a complaint being submitted.
- 2.2. Complaints about the service from the National Office.
- 2.3. Complaints about the procedural conduct of a Committee, or role of a member of a Committee.

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<sup>1</sup> [HRB Customer Service Charter](#)

### 3. What is not covered by the Complaints Policy?

#### 3.1. The Complaints Policy does not cover:

- a. A complaint about the outcome of an ethics assessment of a Committee, in relation to a study. A decision by a Committee can be appealed by following the Appeals Policy,<sup>2</sup>
- b. Complaints relating to any study that falls under the remit of a local or institutional Research Ethic Committee (REC),
- c. Complaints which do not fall within the remit of the National Office and the Committees,
- d. Complaints relating to any REC or REC member which do not fall within the remit of the National Office,
- e. Matters which have already been fully reviewed in accordance with this policy, and
- f. Matters which will be or are currently the subject of legal or police proceedings.

### 4. Definitions

- 4.1. A 'Complainant' is any person making a complaint against one or more Respondents, such as but not limited to, research participants, patients and the public, and researchers.
- 4.2. A 'Complaint' is a formal statement in writing regarding:
  - a. The standard and/or quality of the service provided by the National Office that is not considered acceptable.
  - b. The conduct of a person carrying out a research study approved by a Committee, which is considered unethical.
  - c. The procedural conduct of a Committee or role of a member of a Committee.
- 4.3. The 'Health Products Regulatory Authority' (HPRA) regulates medicines and devices for the benefit of people and animals and is the National Competent Authority in Ireland for regulated research studies.
- 4.4. A 'Respondent' is the person against whom the complaint been made, such as researchers, the National Office and/or the Committees or member of a Committee.

### 5. General Complaints procedure

- 5.1. Complaints shall be handled promptly, sensitively and confidentially.
- 5.2. Complaints should be submitted to the National Office for the attention of:  
Head of the National Office for Research Ethics Committees  
By email: [nationaloffice@nrec.ie](mailto:nationaloffice@nrec.ie)  
By post: Head of the National Office for Research Ethics Committees,

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<sup>2</sup> [Appeals Policy](#)

Health Research Board,  
Grattan House, 67-72 Lower Mount Street  
D02 H638, Ireland

- 5.3. Complaints shall be recorded by the National Office in complaints register and reported to the relevant committee Chairperson. A file note of the complaint will be placed in the relevant file associated with a study, as applicable
- 5.4. Complainants must identify themselves as the National Office cannot investigate anonymous complaints.
- 5.5. Complaints will be reviewed fairly and where appropriate, reviewed by person independent of the activity which is the subject of the complaint.
- 5.6. Complainants must set out the grounds for the complaint in writing.
- 5.7. Upon receipt of a complaint, an acknowledgement will be sent to the complainant within three business days.
- 5.8. The individual(s) that are the subject of the complaint shall be notified of the complaint as it was submitted to the National Office and will be provided with 20 days to respond in writing.
- 5.9. All complaints received will be reviewed and outcomes recorded.
- 5.10. The response received from the individual(s) under Section 5.8 shall form part of the review process.
- 5.11. Complainants will receive an outcome of the review in a timely and efficient manner and best endeavours will be made to do so within 45 business days. Any delays will be communicated to the Complainant.
- 5.12. Where a complaint may require review by the Department of Health, as per Section 8.7, the review timeline may be extended for a further 30 business days. Any delays regarding this additional timeline will be communicated to the Complainant.
- 5.13. The outcome of the review may include the following:
  - a. a summary of the review
  - b. key facts identified
  - c. a conclusion: upholding, partially upholding or not upholding the complaint
  - d. what actions are needed of the Respondents
  - e. how to prevent a reoccurrence, if applicable
  - f. an apology, if required
  - g. information to further assist the Complainant

## **6. Complaints from persons affected by the ethical conduct of a person carrying out a study approved by a Committee**

6.1. In the first instance the Complainant should take the following steps prior to contacting the National Office:

6.1.1. consult with the hospital/study site's policy and procedures for the management of complaints, which may include the following steps for consideration:

- a. contact the Principal/Lead Investigator and/or designated point of contact for the research study,
- b. contact the Sponsor of the study or designated point of contact of the Sponsor,
- c. contact the study site's Data Protection Officer, where the complaint is in relation to a data protection matter; and/or
- d. contact the study sites research management administration services or equivalent, that may be available to the Complainant.

6.2. If the steps taken in Section 6.1.1 yield no resolution for the Complainant, complaints from persons affected by the ethical conduct of a person carrying out research approved by a Committee may be submitted to the National Office and will be referred to the Head of the National Office.

6.3. The complaint shall be managed in accordance with Section 5.

6.4. The Complainant shall set out:

- a. the grounds for the complaint,
- b. the researcher(s) and any other individuals that are the subject of the complaint, and
- c. previous steps taken to seek a resolution to the complaint.

6.5. The National Office shall:

- a. review the nature of the complaint to determine its merit,
- b. consult with the Chairperson of the Committee that approved the research study that is being conducted,
- c. consult with the HPRA in relation to the complaint, or refer the complaint to the HPRA as required,
- d. inform the Sponsors and/or study site, researcher(s) or individuals that are the subject of the complaint in accordance with Section 5.8.

6.6. The National Office reviewing team shall include:

- a. the Programme Manager of the Committee that approved the study referred to by the complainant,
- b. the Chairperson of the Committee that approved the study referred to by the complainant,
- c. the Head of the National Office,
- d. an independent reviewer, as may be required.

6.7. The National Office may, following its review:

- a. dismiss a complaint if it considers it frivolous or vexatious or otherwise without merit
- b. seek to resolve the complaint through informal discussions with complainant,
- c. refer the complaint to the HPRA
- d. vary the ethics opinions with further conditions,
- e. direct that the researcher(s) who is the subject of the complaint to undertake certain actions within a specified timeframe and report when those actions have been taken, and
- f. where no report is made or the Committee is not satisfied with the measures taken it may withdraw the ethics approval, subject to consultation by the HPRA.

6.8. The National Office shall, on concluding its review, report to:

- a. the Committee and the HPRA
- b. the Complainant
- c. the researcher who is the subject of the complaint
- d. the Sponsor of research study, as appropriate

## **7. Complaints about the service from the National Office**

- 7.1. Where a Complainant feels they did not receive as good a service from the National Office as expected, the complaint should be submitted to the Head of the National Office and the National Office team member originally assisting the Complainant.
- 7.2. The complaint shall be managed in the first instance in accordance with Section 5.
- 7.3. The complaint will be reviewed with respect and impartiality and may include an independent reviewer as required.
- 7.4. Where a complaint is deemed to have merit, the National Office will ensure to implement necessary actions to improve its service and such as to avoid such a complaint arising again.
- 7.5. The National Office shall notify the Director Of Corporate Operations of the outcome
- 7.6. Where the Complainant is unsatisfied with the outcome of the review, they have the option to raise the issue with the HRB's Director of Corporate Operations, in accordance with the HRB's Customer Service Charter.
- 7.7. The Director of Corporate Operations can be contacted as follows: Martin Morgan: [mmorgan@hrb.ie](mailto:mmorgan@hrb.ie)

## **8. Complaints about the procedural conduct of a Committee, or role of a Committee member**

- 8.1. All complaints about the procedural conduct of a Committee, member of a Committee in carrying out their role, shall be referred to the Head of the National Office.

- 8.2. The complaint shall be managed in the first instance in accordance with Section 5.
- 8.3. The Chairperson of the Committee and/or member of the Committee, that is the subject of the complaint shall be notified of the complaint, in accordance with Section 5.8.
- 8.4. The complaint shall be reviewed by the Head of the National Office and the Chairperson of the relevant Committee
- 8.5. Where the complaint is in relation to the conduct of a Chairperson, the Head of National Office and the HRBs Director of Corporate Operations shall review the complaint.
- 8.6. Where a complaint is deemed to have merit, the National Office and Committee will implement corrective and /or preventative actions as applicable, to ensure the conduct and procedures that lead to the complaint will not arise again.
- 8.7. Where the Complainant is unsatisfied with the outcome of the review, they have the option to raise the issue with the Department of Health for the attention of the Minister.
- 8.8. The Minister may
  - 8.8.1. remove a Committee member from office, or
  - 8.8.2. uphold the outcome of the review of the National Office and HRB

## **9. Complaints to the Data Protection Commissioner (DPC)**

- 9.1. If a Complainant remains unhappy with the final outcome, and the complaint is in relation to processing and data protection of personal data, they can refer the complaint to the DPC.
- 9.2. The DPC can be contacted in the following ways as set out on its website [How to Contact Us](#)  
The DPC can also be contacted by phone: (01) 765 01 00 and 1800 437 737

## **10. Complaints to the Ombudsman**

- 10.1. If a Complainant remains unhappy with the outcome, they can refer the complaint to the Office of the Ombudsman. The Ombudsman is impartial and free to use.
- 10.2. The Ombudsman will ask for details of the complaint and a copy of the final outcome of the complaints review should be provided. The best way to do this is through:  
'Make A Complaint' at [www.ombudsman.ie](http://www.ombudsman.ie)  
In writing: Office of the Ombudsman, 6 Earlsfort Terrace, Dublin 2, D02 W773.  
Or call 01 639 5600 if there are any queries.

## **11. Questions about the policy**

- 11.1. Any questions about this policy should be referred to the National Office:  
[nationaloffice@nrec.ie](mailto:nationaloffice@nrec.ie)
- 11.2. This policy shall be reviewed every two years, and revise sooner if required.

### Version Control Sheet (VCS)

<b>Policy Title</b>	Complaints Policy & Procedures
<b>Policy Owner and Title</b>	Emily Vereker, Head of Office
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- ☒ Information for stakeholders
- ☒ Requirement under legislation

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V1	30 September	Emily Vereker	Complaints Policy and Procedures for the National Office	HRB Executive Team NREC Chairs