

# HRCDC Complaints Policy

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## 1. Background

The Health Research Consent Declaration Committee (the 'HRCDC') endeavours to carry out its role with professionalism and to the highest quality.

The HRCDC ('Committee') are committed to making a consent declaration where the public interest in conducting the research significantly outweighs the requirement to obtain explicit consent from research participants. The HRCDC Secretariat team are responsible for supporting the Committee in this role.

We acknowledge that matters may arise in relation to the work of the HRCDC Secretariat and Committee, 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 HRCDC will make every effort to coordinate all complaints and assist all Complainants, as fairly as possible.

As the HRCDC 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 HRCDC policy and procedures for:

- 2.1. Complaints about the conduct of a person carrying out a study approved by the HRCDC (hereinafter 'Committee(s)')
- 2.2. Complaints about the service from the HRCDC.
- 2.3. Complaints about the procedural conduct of the Committee, or role of a member of the 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 application assessment of the Committee, in relation to a study. A decision by the Committee can be appealed by following the Appeals Policy,<sup>2</sup>
- b. Complaints which do not fall within the remit of the HRCDC.
- c. Matters which have already been fully reviewed in accordance with this policy, and
- d. Matters which will be or are currently the subject of legal or law enforcement proceedings.

### 4. Definitions

4.1. A 'Complainant' is any person making a complaint against one or more Respondents.

4.2. A 'Complaint' is a formal statement in writing regarding:

- a. The standard and/or quality of the service provided by the HRCDC that is not considered acceptable.
- b. The conduct of a person carrying out a research study approved by the Committee.
- c. The procedural conduct of the Committee or a member of the Committee.

4.3. A 'Respondent' is the person against whom the complaint has been made, such as researchers, the HRCDC or Secretariat.

### 5. General Complaints procedure

5.1. Complaints shall be handled promptly, sensitively and confidentially.

5.2. Complaints should be submitted to the HRCDC Secretariat, for the attention of:  
Chairperson of the Health Research Consent Declaration Committee

By email: [secretariat@hrcdc.ie](mailto:secretariat@hrcdc.ie)

By post: Chairperson of the Health Research Consent Declaration Committee,  
Health Research Board,

Grattan House, 67-72 Lower Mount Street

D02 H638, Ireland

5.3. Complaints shall be recorded by the Secretariat in a complaints register and reported to the Chairperson. A file note of the complaint will be placed in the relevant file associated with a study, as applicable

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

- 5.4. Complainants must identify themselves as the HRCDC cannot investigate anonymous complaints.
- 5.5. Complaints will be reviewed fairly and where appropriate, reviewed by a 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 HRCDC and will be provided with 20 working 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 conduct of a person carrying out a study, approved by HRCDC.**

- 6.1. In the first instance the Complainant should take the following steps prior to contacting the HRCDC:
  - 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;
- 6.2. If the steps taken in Section 6.1.1 yield no resolution for the Complainant, complaints from persons affected by the conduct of a person carrying out the research approved by a Committee may be submitted to the HRCDC and will be referred to the Chairperson of the HRCDC.
- 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 HRCDC Secretariat shall:
  - a. review the nature of the complaint.
  - b. consult with the Chairperson of the HRCDC
  - c. consult with the Data Protection Commission (DPC), if appropriate, in relation to the complaint, or refer the complaint to the DPC 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 HRCDC complaint reviewing team shall include:
  - a. Programme Manager of the HRCDC.
  - b. Chairperson of the HRCDC
  - c. an independent reviewer, as may be required.
- 6.7. The HRCDC team as above 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. vary the applicable consent declaration with further conditions,
  - d. 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
  - e. where no report is made or the Committee is not satisfied with the measures taken it may revoke the consent declaration.
- 6.8. The HRCDC team shall, on concluding its review, report to:
  - a. the Committee
  - b. the Complainant

- c. the researcher who is the subject of the complaint
- d. the Sponsor / Controller of research study, as appropriate

## **7. Complaints about the service from the HRCDC / Secretariat**

- 7.1. Where a Complainant feels they did not receive as good a service from the HRCDC as expected, the complaint should be submitted to the Chairperson of the HRCDC and the Secretariat 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 HRCDC will ensure to implement necessary actions to improve its service and such as to avoid such a complaint arising again.
- 7.5. The HRCDC shall notify the HRB 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 the 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 Chairperson of the HRCDC.
- 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 Chairperson of the HRCDC
- 8.5. Where the complaint is in relation to the conduct of the HRCDC chair, the HRBs Director of Corporate Operations shall review the complaint.
- 8.6. Where a complaint is deemed to have merit, the HRCDC 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 HRCDC 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 HRCDC: [secretariat@hrcdc.ie](mailto:secretariat@hrcdc.ie)

11.2. This policy shall be reviewed every two years, and revise sooner if required.