

Health Research Consent Declaration Committee – Appeal process.

1. Introduction

The Health Research Regulations (S.I No 314 of 2018 and as amended), made by the Minister for Health in August 2018 under section 36(2) of the Data Protection Act 2018, provide for an application for a consent declaration to be made to the Health Research Consent Declaration Committee (HRCDC).¹ The Regulations further provides for an applicant to appeal a decision of the HRCDC through an independent ministerially appointed appeal panel that is wholly separate and independent from the HRCDC.

2. Purpose and scope

2.1 Regulation 11 of the Health Research Regulations 2018² and as amended³ provides the legislative framework for an appeals procedure. This document sets out the independent appeals process which follows where an applicant to the HRCDC wishes to appeal a decision of the Committee.

2.2 The appeals process is separate from and independent of the HRCDC and an applicant can consider an appeal in cases where:

- The HRCDC refuses to make a declaration (under Regulation 8(4)(c))
- The HRCDC attaches conditions to a declaration under (Regulation 8(4)(b)), or
- The HRCDC revokes a declaration (under Regulation 10(1)) where it is satisfied that the conditions attached to a declaration are not being met.

3. Informal engagement with the HRCDC prior to starting an appeal.

3.1 Before formalising a notice of appeal to the Minister, applicants are encouraged to contact with the Secretariat of the HRCDC to seek clarifications or further details.

3.2 Applicants should contact the Programme Manager, who together with the Chairperson of the HRCDC, may provide additional clarification to address any queries, that may be pertinent to the decision to proceed with the appeal. Subject to the nature of the Applicant's response, the matter may also be raised or highlighted to the full committee.

3.3 This contact from the Applicant to the Secretariat must be made as soon as possible and within five working days of receipt of the decision from the HRCDC.

4. How to make an appeal

4.1 The decision letter issued by the HRCDC Secretariat to the applicant will advise of an applicant's right to appeal a decision. The applicant may, within 30 working days from the date of the letter setting out the decision from the HRCDC, give notice to the Minister and the HRCDC of his/her intention to appeal that decision (becoming the "Appellant") and request the Minister to establish an appeal panel.

¹ www.hrcdc.ie

² <https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf>

³ <https://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf>

4.2 Formal notice of the appeal shall be sent by the Appellant to the following email address secretariat@hrcdc.ie. The HRCDC shall inform the Department of Health (DOH) of the notice as soon as is practicable.

4.3 The Appellant should include the following in the notice of appeal:

- A cover letter formally requesting the Minister to establish an appeal panel and setting out in detail the identified grounds for the appeal.
- Any relevant additional evidence that may support the appeal (an Appellant may indicate when submitting the appeal that they intend to send further evidence in support of the appeal in follow-ups to the initial email).

4.4 When a notice to appeal is received, an acknowledgement will be sent to the Appellant by the HRCDC secretariat. The DOH shall form the appeal panel. The Secretariat will also notify the Appellant of when the appeal panel is established.

4.5 The Secretariat will provide administrative assistance to the appeal panel. It is also important to note that the Secretariat will not conduct any reviews or offer any opinion on the information provided by the Appellant or the appeal panel.

4.6 The individual named in the original application to the HRCDC as the lead contact person (of which there can only ever be one at any time) shall be presumed to be the lead contact person for the appeal unless the Appellant makes it clear that another named individual is to be so regarded.

5 The Appeal Panel

5.1 The Minister for Health shall establish an appeal panel within 60 working days of the date of the receipt of the formal notice from an appellant.

- The appeal panel shall consist of at least 5 but not more than 7 persons, one of whom shall be appointed as the Chairperson.
- One member of the appeal panel will be a Patient, Public and Carer Involvement representative.
- Members of the appeal panel should have suitable expertise and lived experiences having regard to the functions of the appeal panel.
- No member of the appeal panel will have had any prior involvement in the issues in an appeal where such an involvement might, or might be perceived to, involve a conflict of interest or compromise his/her ability to consider the appeal in a fair and objective manner.
- No member of the appeal panel shall be a person who is a current member of the HRCDC.
- The Secretariat will engage with the appeal panel members to provide them with all relevant documentation, including,
 - a copy of the application to the HRCDC and
 - any supplemental documents submitted to the HRCDC, including pre-submission advice, Secretariat queries and applicant responses.
 - a copy of the decision letter from the HRCDC which is the subject of the appeal.
- Where the appeal panel requires more information than was included in the submission, the Chairperson will inform the Secretariat and they will communicate directly with the appellant.
- The appeal panel can request from the HRCDC Secretariat, the application file documentation, that was submitted initially.

- The appeal panel may also request a submission from the HRCDC in reply to the appeal and any additional documentation the Appellant may provide to support their appeal (if this is additional to that already reviewed by the HRCDC).
- The appeal panel may invite written submissions from any person it considers appropriate and may consult with any person who it believes could assist in the consideration of an appeal.
- The appeal panel will complete the appeal process by review of documentation from the Appellant and HRCDC
- An appeal should be considered by the appeal panel as soon as practicable following the establishment of the appeal panel.
- An appeal panel shall determine its own procedure and inform the HRCDC Secretariat of same

5.2 The Chairperson of the appeal panel will inform the Secretariat of the decision as soon as practicable after the decision is made and the reasons for it. The decision by the appeals panel may be any of the following:

- (i) confirm the HRCDC's decision and not make a declaration or
- (ii) allow the appeal and make a declaration or
- (iii) vary the HRCDC decision.

5.3 The Appeal panel shall stand dissolved 30 working days after notification of its decision.

6. Communicating the Appeal Panel Decision

The Secretariat shall inform the Appellant of the decision in writing and the reasons for it.

- The HRCDC website will be updated in a timely manner with the date of an appeal, the membership of an appeal panel, the appeal decision and the reasons for it together with any minutes of the appeal panel in relation to the appeal.
- The appeal panel decision is final.

7. Review of declarations made by an appeal panel

In accordance with The Health Research Regulations (S.I No 314 of 2018 and as amended), the HRCDC may review the operation of declarations made by it or by an appeal panel under these Regulations from time to time and may, for the purpose of that review, seek information from a person to whom a declaration was granted in relation to any aspect connected with the operation of that declaration. A person to whom a declaration is made is required to co-operate with the HRCDC with any review or risk having the declaration revoked.