



Health Research Regulations Appeals process from decisions of the Health Research Consent Declaration Committee

Introduction

The Health Research Regulations (S.I No 314 of 2018), 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 a Committee established by the Minister to consider and make decisions on such applications. That Committee – known as the Health Research Consent Declaration Committee (HRCDC) - was established earlier this year and is operational. The Regulations also provide for an appeal from decisions of the HRCDC to an appeal panel that is wholly separate and independent from the HRCDC and is appointed by the Minister for the purposes of hearing the appeal. The Minister and his or her Department are not involved in any way in the decision making process on appeals made.

Purpose of this document

This document sets out the independent appeals process which follows where the applicant to the Health Research Consent Declaration Committee wishes to appeal the decision of the Committee. Provision for an appeal by the applicant and the procedure to be followed is provided for in Regulation 11 of the Health Research Regulations 2018.

The appeals process is wholly separate from and independent of the HRCDC and can consider requests for 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 imposed by it are not being met.

As per Regulation 11(5), the appeal panel will, having considered an appeal-

- (a) confirm the decision,
- (b) vary the decision, or
- (c) allow the appeal.

How to make an appeal

- The decision letter issued by the HRCDC secretariat to the applicant setting out the decision of the HRCDC in respect of the application for a consent declaration (or, where appropriate, the letter to the person notified of the decision to revoke a consent declaration made) 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.
- The Regulations do not provide any discretion in terms of timeframe for notifying the Minister of the intention to appeal.
- As the appeals panel is not a standing committee (like the HRCDC) it does not have its own dedicated secretariat. Accordingly, an officer in the Department of Health will serve as the point of contact on behalf of the Minister for all correspondence with the appellant, the appeal panel and the HRCDC secretariat and for reference purposes he or she shall be known as the appeals officer.
- A person making an appeal should do so by email to the following dedicated address HRCDCappeals@health.gov.ie In this email to the appeals officer, the appellant should include:
 - 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.
 - A statement 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).
- When a notice to appeal is received, an acknowledgement will be sent to the appellant by the appeals officer. The appeals officer will, when in a position to do so, also notify the appellant of when the appeal will be considered by the appeal panel so that the appellant can ensure that he or she submits all documentation in good time.
- 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. Documentation in relation to the appeal should not be submitted to the appeals officer by any other person purporting to act on behalf of the person making the appeal. If it is, it will be returned and may delay the hearing of the appeal.



The Appeal Panel

- The Minister shall establish an appeal panel within 40 working days of the date of the receipt of the request from an appellant.
- The appeal panel shall consist of at least 3 persons, one of whom shall be appointed as the Chairperson.
- Members of the appeal panel should be suitably qualified 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 appeals officer will engage with the appeal panel members to provide them with all relevant documentation.
- Members of the appeal panel are bound by a duty of confidentiality in the course of the work of the panel.
- Where the appeal panel requires more information than was included in the submission, the Chairperson will inform the appeals officer and the appeals officer will communicate directly with the appellant.
- Appeals panel can request from the HRCDC the application file documentation that was submitted initially.
- 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.
- The Chairperson of the appeal panel will inform the appeals officer of the decision as soon as practicable after the decision is made and the reasons for it.
- An appeal panel, having considered the appeal and having made a decision and notified the appeals officer, shall stand dissolved.

Communicating the Appeal Panel Decision

The appeals officer, on behalf of the appeal panel, shall inform the appellant and the HRCDC secretariat of the decision in writing and the reasons for it.

- Where the decision of the appeals panel differs from the decision of the HRCDC, the appeal panel may request the appeals officer to forward, where appropriate, such information that was submitted to it as part of the appeals process that was not submitted to the HRCDC.
- 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.



Review of declarations made by an appeal panel

It should be noted that the Regulations provide that 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.

1 August 2019