HREA Complaints Policy	HREA-GEN03
Issuing Authority	Health Research Ethics Authority
Signature of Administrative Authority Chairperson, HREA	Regna Coady
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Approval Date	July 2025
Scheduled Review Date	July 2028

Background: The Health Research Ethics Authority (HREA) was established to ensure that all health research conducted with human participants in Newfoundland and Labrador is conducted in an ethical manner and to enhance public awareness of the ethical dimension of health research. The HREA is committed to maintaining accountability, as well as the trust and respect of all individuals and stakeholders affiliated with the HREA.

The HREA recognizes that there may be concerns or complaints that arise and that a process for reporting them is required.

A complaint is an expression of dissatisfaction associated with the business of the HREA. The complaint may be related to the Health Research Ethics Board (HREB), Appeals Board, committees and/or individuals affiliated with the HREA, including HREB members, Appeal Board members, committee members, Ad hoc advisors, Researchers and Research Ethics Office (REO) personnel.

Complainants can choose to resolve their complaint through a formal or informal process. A formal complaint must be made in writing and will be resolved through a process that includes a formal response. An informal complaint may be made verbally and will be resolved informally and expeditiously through verbal or written communication.

Scope: This policy applies to complaints related to the HREB, Appeals Board, committees and/or individuals affiliated with the HREA, including HREB members, Appeal Board members, Ad hoc advisors, committee members, Researchers, and REO Personnel.

The policy is intended to be complementary to other policies and collective agreements governing the conduct of individuals affiliated with the HREA.

This policy does not apply to a review decision of the HREB or an appeal board. This process is addressed in policies HREB Review (HREB-REB03) and Authority of Appeal Panel (HREA-AP01).

This policy does not apply to Human Resources matters covered under other policies such as Respectful Workplace, Equity, Diversity and Inclusion and Harassment policies.

Purpose: The purpose of the Policy is to ensure that complaints received by the HREA are dealt with in a timely, consistent, and fair manner.

Policy Statements:

- 1. All complaints received by the HREA will be reviewed in a timely, consistent, and fair manner. The process for submitting, receiving, reviewing, and resolving complaints received by the HREA is outlined in this policy.
- All matters relating to this policy shall be handled with confidentiality and in accordance with
 the <u>Access to Information and Protection of Privacy Act, 2015</u>, HREA policies and any other
 privacy legislation to which the HREA is subject. All persons involved in any process related to
 this Policy shall maintain confidentiality unless reporting is mandatory under other provincial or
 federal legislative requirements.
- **3.** In the interest of workplace safety and wellbeing, the HREA will not respond to threatening or abusive phone calls, emails or messages.

PROCEDURE:

Informal Complaints

Informal complaints may be communicated to the HREA Ethics Director.

Complaints regarding the Ethics Director may be communicated to the Chairperson of the Authority.

The Ethics Director or Chairperson of the Authority, as applicable, shall attempt to resolve the complaint through verbal or written communication with the complainant. This process will usually not exceed one month.

Complainants will be advised verbally or in writing if the complaint falls outside the scope of this policy, such as workplace harassment. Such complaints should be resolved via the applicable policy.

If the complaint cannot be resolved informally, it will be escalated to a formal complaint.

Formal Complaints

Formal complaints shall be reported in writing and sent to the Ethics Director.

Formal complaints regarding the Ethics Director shall be reported in writing and sent to the Chairperson of the Authority.

Complainants will be advised in writing if the complaint falls outside the scope of this policy, such as workplace harassment.

A Formal Complaint shall contain the following information:

- a. Name and contact information of complainant
- b. Date of complaint
- c. Reference Number of study protocol, if applicable to the nature of the complaint
- d. Description of the complaint
- e. Whether efforts have been made to resolve the issue

The Chairperson of the Authority or Ethics Director, as applicable, shall acknowledge receipt of the formal complaint in writing to the complainant within three (3) business days. The Chairperson of the Authority or Ethics Director, as applicable, shall consider the complaint in detail, which may include the following:

- Discussing the issue with the applicable individual(s)
- Seeking further information and clarification from the complainant as required

The Chairperson of the Authority or Ethics Director, as applicable, shall attempt to resolve the complaint in a timely manner. Complainants will be informed of the status of their complaint.

Related Documents:

Access to Information and Protection of Privacy Act, 2015

Health Research Ethics Act: An act respecting health research ethics. (2025). Retrieved from: SNL2024 CHAPTER H-1.03 - HEALTH RESEARCH ETHICS ACT[In force July 1/25]

VERSION HISTORY

Revision Date	Summary of Changes
March 2022	Original version
April 2024	No revisions required
July 2025	Health Research Ethics Act 2025