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གསོ་སྦྱང་ལྷན་ཁག་
ཤེས་རིག་གི་འཕུལ་སྤྱོད་ལྷན་ཁག་
ཐིམ་ཕུ་

ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
RESEARCH ETHICS BOARD OF HEALTH
THIMPHU : BHUTAN
P.O. BOX : 726



Standard Operating Procedure (SoP) for Complaint Management and Redressal; Research Ethics Board of Health

Purpose

To establish a transparent, timely, fair, confidential process for receiving, assessing, investigating, resolving, and monitoring complaints related to research reviewed or overseen by the Research Ethics Board (REB).

Scope

Applies to all complaints involving human research ethics, investigators, REBH members, staff, participants, sponsors, and institutions.

Definitions

Complaint: expression of dissatisfaction.

Complainant: person submitting complaint.

Respondent: subject of complaint.

Conflict of Interest: any circumstance impairing impartiality.

Principles

Confidentiality, fairness, independence, protection from retaliation, proportionality, transparency, documentation.

Roles

REBH Chair oversees; Secretariat receives/logs; Investigation Panel investigates; Institution implements corrective actions.

Procedure

1. Receive complaint (email, letter, phone, in person).
2. Acknowledge within 5 working days.
3. Register complaint and assign case ID.
4. Preliminary assessment within 10 working days: admissibility, urgency, conflict of interest.
5. If accepted, appoint independent panel (2–3 members excluding conflicted persons).
6. Notify respondent and obtain written response within 10 working days.
7. Collect evidence: protocols, consent forms, correspondence, interviews where needed.
8. Panel deliberation and findings.



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ཤེས་ལུགས་

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9. Decision by REBH Chair/Board.
 10. Communicate outcome within 45 working days where feasible.
 11. Implement corrective/preventive actions.
 12. Close case after verifying completion.

Possible Outcomes

Dismissal, mediation, corrective action plan, protocol modification, suspension of approval, termination, referral to institutional or regulatory authority.

Appeals

Appeal within 15 working days based on procedural error, new evidence, or disproportionality. Independent appeal panel reviews within 30 working days.

Confidentiality

Maintain secure records; share information only on a need-to-know basis.

Record Keeping

Retain complaint files, evidence, decisions, and correspondence for at least 10 years or according to national requirements.

Monitoring

Annual trend analysis, CAPA tracking, periodic SOP review every 3 years.

KPIs

Acknowledgement ≤ 5 days; assessment ≤ 10 days; closure target ≤ 45 days; % CAPAs completed on time; repeat complaint rate.