



Standard Operating Procedures
Research Ethics Committee (Human) (REC-H)

- **Complaints process**

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1 COMPLAINTS PROCESS

1.1 TYPES OF COMPLAINTS

1. The REC-H may receive complaints about researchers, the conduct of research, or about the conduct of the REC-H. Complaints may be made by participants, researchers, staff of the institution, or others. All complaints should be handled promptly and sensitively.
2. Possible complaints cover a broad spectrum from 'inadvertent technical deviations' from established protocols to allegations of scientific misconduct or fraud. The primary concern in response to any complaint is the extent to which research participants are endangered. There may also be concerns about the degree to which researchers are fulfilling their responsibilities, questions around culpability for misconduct and misleading reports being published by a researcher accused of misconduct or fraud. Often the REC-H will be the most appropriate body to consider complaints in the first instance, although ultimately, the responsibility lies with Nelson Mandela University.

1.2 PROCEDURES FOR RECEIPT OF COMPLAINTS

1. A complaint should be lodged with the REC-H Administrator. The REC-H Administrator will forward the complaint on to the REC-H Chairperson.
2. Submissions from whistle-blowers will be confidential and can be made to the REC-H Chairperson.
3. The Chairperson of the REC-H will receive the complaints; he/she may delegate this responsibility to a member of the REC-H. All complaints will be dealt with and may require the assistance of other persons (not necessarily members of the REC-H).
4. Should any person feel that the response of REC-H is inadequate, a complaint can be escalated to the DVC: RII at dvc-rii@mandela.ac.za, and thereafter the National Health Research Ethics Council (NHREC), to which REC-H is affiliated.

1.3 PROCEDURES FOR RESPONDING TO COMPLAINTS

1. The Chairperson would consider the complaint - including, where necessary, reference to original protocol, contact with researchers, or contact with complainants.
2. The Chairperson will respond urgently when there is any suggestion of harm to research participants, researchers, or any other person. In extreme circumstances, an immediate demand to suspend a research study may be necessary while concerns are adequately investigated. In other cases, prompt action may be required to rectify or remove the cause of concern. Having determined the urgency of the need for action, the Chairperson should take any, and possibly all, of the following steps according to the circumstances:
 - a. Make a clear and full written record of the complaint.
 - b. Seek further information from all relevant parties.
 - c. Notify the PI and PRP of the complaint and request a written response, which will serve at the next meeting of the REC-H or at an urgent meeting of the REC-H, which will be convened if necessary.
 - d. If necessary, confer with the highest level of management and authority within the relevant institution.
 - e. Advise the complainant of the response.

1.4 PROCEDURES FOR INVESTIGATING COMPLAINTS

1. Where initial investigations reveal a situation that requires further investigation and review, the following procedures are recommended, at the discretion of the REC-H Chairperson:
 - a. Table the investigation report at the next REC-H meeting.

- b. In addition to the written response from the researcher, invite the researcher(s) to explain the situation to the REC-H and to demonstrate why the project should not be discontinued and ethical approval withdrawn.
 - c. Advise researcher(s) that they may be accompanied by one or more colleagues.
 - d. Reconsider the original research proposal and seek additional information from the researcher(s) in relation to the conduct of the study, or any other relevant factors, before making a final decision whether to **revise** or **reconfirm** the original decision to approve the project.
 - e. Having considered the matter, the committee may:
 - i. **withdraw approval** resulting in suspension of the project,
 - ii. **require amendments** to the original research proposal or to the conduct of the research, or
 - iii. allow the project to continue without amendment.
2. The REC-H will inform the principal investigator/researcher in writing of the decision of the REC-H explaining the reasons for the recommendations. It may be necessary to inform research participants that the research they have been participating in has been modified or discontinued. In this instance, the REC-H will take advice from the researcher(s) about the wording of the notice to participants.
 3. An appeal against a decision can be made and should be referred to a mediator independent of the REC-H and related activities.
 4. Advise the complainant of the response. Where the complainant is not satisfied with the actions taken, the complaint could be referred to the DVC: RII.

1.5 ALLEGATIONS AND COMPLAINTS OF SERIOUS RESEARCH MISCONDUCT

1. Research misconduct includes any of the following:
 - a. Fabrication, falsification, plagiarism, or deception in proposing, carrying out, or reporting results of research.
 - b. Deliberate, dangerous, or negligent deviations from accepted practice in carrying out research. This includes failure to follow established protocols if this results in unreasonable risk or harm to human beings, animals, or the environment and also the facilitating of misconduct by collusion in, or concealment of, such actions by others.
 - c. Failure of informed consent.
 - d. Breaches of confidentiality.
 - e. Deception in research process.
 - f. Misrepresentation or falsification of credentials.
2. Misconduct does not include honest error or honest differences in the design, execution, interpretation, judgment in evaluating research methods or results of misconduct (including gross misconduct) unrelated to the research process.
3. Where there has been an allegation of serious misconduct, the institution should ensure the following:
 - a. Protection of participants.
 - b. Appropriate confidentiality (in case the allegation proves to be groundless).
 - c. Protection of 'whistle-blowers'.
 - d. Natural justice for those who are the subject of any allegations or complaints.
4. Confidentiality, protection for complainants and natural justice for the person complained about will be dealt with by the review process outlined as follows:
 - a. Determine whether the allegation falls within scientific misconduct.
 - b. Determine whether there is prima facie evidence of scientific misconduct.
 - c. Institute a formal investigation to evaluate all relevant facts to determine whether scientific misconduct has been committed and, if so, by whom, as well as the seriousness of the misconduct. The integrity of the research data must be evaluated, and all appropriate groups advised if inaccurate, misleading or invalid data have been published or submitted to other agencies.

1.6 COMPLAINTS CONCERNING REC-H REVIEW PROCESSES

1. Most complaints received by REC-H concern the review process itself or the manner in which researchers and their projects have been considered and dealt with. For example, researchers may complain when the REC-H has rejected a proposed project, when a committee is perceived to be taking undue time considering a proposal, or when conflict has arisen between a committee and researchers. In many situations, the problem may simply be one of inadequate communication between the committee, its administrators, and the complainant(s).
2. The Chairperson will attempt to deal with the concern or complaint without formal investigation where possible.
3. If the matter remains unresolved, the principle investigators may lodge a formal complaint with the Deputy Vice-Chancellor: RII.
4. If the complainant is dissatisfied with the decision of the Deputy Vice-Chancellor: RII, an appeal may be lodged with the Vice-Chancellor. The decision of the Vice-Chancellor is final and binding.