

HREC Procedure

Suspension or Withdrawal of Approval for Conduct of Research Projects

Purpose:

To describe the procedure for suspension or withdrawal of ethical approval by the Human Research Ethics Committee (HREC).

Scope:

This procedure applies to all current research projects which have received approval from HREC.

Procedure / Method:

1. Where the HREC has reason to believe that continuance of a research project will compromise participants' welfare, or that a research project is not being or cannot be conducted in accordance with its ethical approval, it should immediately establish whether ethical approval for the project should be suspended or withdrawn. In pressing circumstances, the HREC Chair may suspend approval. The HREC Chair must convene, as soon as practicable, a sub group of the HREC with expertise aligned to the area of suspended research to confirm the suspension. In such circumstances, the suspension shall be until the next scheduled HREC meeting where the suspension may be extended, ceased or the project's ethical approval permanently withdrawn.
2. Whenever a project is suspended, the Research Office (RO) will immediately notify the Principal Investigator (PI) of the suspension of the ethical approval including details of reasons for suspension.
3. An Investigator cannot continue with the research if ethical approval has been suspended and must comply with any special conditions imposed by the HREC. The research may not be resumed unless either:
 - The Investigator subsequently establishes to the HREC that continuance will not compromise participants' welfare and/or is to be conducted in accordance with its ethical approval; or
 - The research is modified to provide sufficient protection for participants, the modification is ethically reviewed, and the modified research is approved by the HREC.
4. The HREC, after consideration at a meeting, makes the final decision with regards to reinstatement or withdrawal of ethical approval. The PI is notified in writing of the decision within 5 working days of the HREC meeting.
5. In the case of suspension or withdrawal of ethical approval, the RO will notify the Executive Director Medical Services.
6. The RO will update the status of the project on the research database.
7. In the case of withdrawal of ethical approval, the PI and the RO will cooperate to inform research participants involved in the study when possible.

Outcome:

To ensure research participant safety and that all research projects are conducted in accordance with their ethical approval.

Standards:

National Statement on Ethical Conduct in Human Research (NHMRC 2007 and as amended)

National Standard 1 – Governance (NSQHS)

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Linked Policy & Procedure:

Research Policy

Approval / Committees:

This procedure was approved by the Human Research Ethics Committee and Executive Director Medical Services/Chief Medical Officer.

Responsible Executive:

Executive Director Medical Services/Chief Medical Officer

Evaluation:

This procedure will be reviewed by the HREC to comply with current legislation, regulations, industry standards, guidelines, codes of conduct and codes of ethics.

Policy / Procedure Review:

This procedure will be reviewed triennially.

Key Words for Search:

HREC, research, withdrawal, suspension

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Procedure Details:

Details		
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