PROCEDURE

HREC Procedure Suspension or Withdrawal of Ethical Approval for Conduct of Research Projects

Purpose:

To describe the procedure for suspension or withdrawal of ethical approval by the Royal Victorian Eye and Ear Hospital Human Research Ethics Committee (HREC).

Scope:

This procedure applies to all current research projects which have received approval from the Royal Victorian Eye and Ear Hospital's HREC.

Risks/Precautions:

None have been identified at the time of this review.

Procedure/Method:

1. Ethics approval for a project may be withdrawn where the HREC has reason to believe that continuance of a research project will compromise participants' welfare, or that a research project is not being or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, or that there has been serious non-compliance with procedures or regulations. In these circumstances, the HREC should immediately establish whether ethical approval for the project should be suspended or withdrawn.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next scheduled HREC meeting where the suspension may be extended, ceased or the project's ethical approval permanently withdrawn.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), the Approving Authority (institution), the sponsor (if relevant), and the TGA as applicable, 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:
    - 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; or
- All regulatory matters outstanding have been resolved

4. The HREC, after consideration at a meeting, makes the final decision with regard to reinstatement or withdrawal of ethical approval. The PI, Approving Authority, sponsor (if relevant), and TGA as applicable, are 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 Eye and Ear 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, the RO, the institution affiliated with the PI and the sponsor (if a clinical trial) must cooperate to ensure the safety of participants of the research project. A plan must be provided to the HREC and the RO detailing what the participants will be told and what options are available to them to continue their care.

Outcome:

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

Standard:

NSQHS Standard 1: Clinical Governance

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

Legislation:

Current Legislation may be sourced at: http://www.austlii.edu.au/ or Victorian legislation at: https://www.legislation.vic.gov.au/

None have been identified at the time of this review.

References:

None have been identified at the time of this review.

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

Document Author:

Research Manager

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.

Procedure Review:

This procedure will be reviewed at least every 3 years.

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Details	
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