Purpose

This document provides guidance to researchers, sponsors and the HREC on the circumstances in which ethical approval may be suspended or withdrawn, and the action required in the event that this occurs, as per chapter 5.5 of the National Statement on Ethical Conduct in Human Research (2007 incorporating all updates).

Definitions

Suspension of HREC approval: an immediate and temporary halt in HREC approval of some or all research activities.

Withdrawal of HREC approval: an immediate and permanent halt in HREC approval of all research activities.

Guidance

The HREC may become aware of information that raises concerns about a study. The information usually comes from the Operations Manager, Committee Manager, Chair, a Committee Member or a Site Monitor.

The Chair has the right to suspend or withdraw ethical approval on behalf of the Committee.

Ethical approval may be withdrawn or suspended in any of the following circumstances:

- if the project is not being conducted according to the approved protocol;
- if serious misconduct by an investigator is suspected or proven;
- if the investigator fails to inform the HREC of adverse reactions resulting from the current study, or of new safety information from other published or unpublished studies that may affect the acceptability of the trial;
- if the wellbeing of any participant or participants is compromised;
- if the investigator is failing or has failed to comply with any conditions imposed by the HREC;
- if a clinical hold has been placed on the study by the US Food and Drugs Administration (FDA) or Therapeutic Goods Administration (TGA), or other regulatory body;
- if a sponsor or investigator remains unresponsive to the HREC's request for information.

If the HREC Chair receives information that suggests and considers that any of the above circumstances may have occurred or are occurring, they will send a letter to the investigator requesting more information and responses to any questions. The Chair will ask for a response within a specified time frame.

If upon considering this information the Chair recommends withdrawal or suspension of ethical approval of the study, the Chair will write to the researcher clearly stating the reasons for the decision. Recommendations for further action and any necessary steps will be explained in the letter.

If ethical approval is suspended or withdrawn, Bellberry requires that:

- the investigator informs their institution, sponsor and where possible, the participants;
- any correspondence to participants be reviewed and approved by the Bellberry HREC before it is sent;
- the institution ensure that the investigator promptly suspends the research and makes arrangements to meet participants' needs;

- the research not be resumed unless and until the researcher establishes that continuance will not compromise participants' welfare, and/or the research is sufficiently modified to protect participants, with any modifications reviewed and approved by the HREC.

In the event that a researcher has terminated or suspended the clinical trial without the prior agreement of the sponsor, the researcher must inform the HREC without delay. The Principal Investigator is responsible for ensuring the fulfilment of the requirements listed directly above.

References

National Statement on Ethical Conduct in Human Research (2007 incorporating all updates)