POLICYI020 MONITORING – WITHDRAWAL OR SUSPENSION OF ETHICAL APPROVAL

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PURPOSE

To describe the process required for withdrawal or suspension of ethical approval in cases where participants' welfare may be compromised as per the National Statement **Chapter 5.5.7.**

1. Researchers are required to report to the HREC as soon as possible any adverse reactions from the current study that may have an impact on the continued acceptability of the trial or may indicate the need for an amendment to the trial protocol.
2. Researchers are required to inform the HREC as soon as possible of any new safety information from other published or unpublished studies that may have an impact on the continued ethical acceptability of the trial or may indicate the need for amendments to the trial protocol.
3. The Operations Manager, Committee Manager, Chairs, Committee members or Site Monitor may bring new information to the attention of the HREC that may raise concerns regarding the study.
4. Ethical approval of a project may be withdrawn or suspended in any of the following circumstances:
    - if the project is not being conducted in accordance with the approved protocol;
    - if serious misconduct by an investigator is suspected or proven;
    - if the investigator is failing to comply with any conditions imposed by the HREC;
    - if a clinical hold has been placed on this study by either the FDA or TGA;
    - Sponsor remains unresponsive to HREC requests directed through the Principal Investigator
5. Upon receipt of any such information this must be forwarded to the relevant Chair and committee members who provided the initial review of the study. The members must determine the relevance of the information and determine if questions should be asked of the investigator.
6. If required, a letter must be sent to the investigator requesting his/her view of the information, and asking for a response to any questions within a specified time frame.
7. The researcher's responses should be sent to all relevant members for feedback. If necessary a teleconference can be arranged so that members can have an open discussion.
8. If withdrawal or suspension of ethical approval of the study is recommended this will be made in writing to the researcher clearly stating the reasons for the withdrawal or suspension. Any recommendations or necessary steps to be taken should be included. Immediate correspondence with the participant will be recommended. Any correspondence to be sent to the participant must first be reviewed by the HREC.
9. The correspondence will be viewed by the full committee at its next meeting.