HREC Standard Operating Procedure

5.13 Monitoring Approved Research

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 5 of the National Statement on Ethical Conduct in Human Research (2023) by ensuring approved research is monitored appropriately.

Definitions

Monitoring is defined as the process of verifying that the conduct of research conforms to the approved proposal.

Procedures

Annual Reporting

In order to ensure that the conduct of research conforms to the approved proposal, Investigators are required to submit a detailed annual progress report on the 1st May every year. Receipt and approval of this report will be issued in the form of written correspondence. This is a condition of approval, which is listed on the letter of final approval.

To facilitate this process, a reminder will be sent from the Research Governance Unit to the Investigator approximately one month prior to the due date. If the report continues to remain outstanding, a subsequent reminder letter will be sent one month after the due date to stipulate that urgent attention is required. If the report is not submitted within 45 days of the annual report submission date of 1st May, ethical and/or governance approval may be withdrawn.

For projects conducted at SVHM and approved by an external HREC, a Site Report/Closure Form (RGO) report is required to detail the study progress.

If the study has been approved by the SVHM HREC via the multisite approval pathway, the CPI or Sponsor is responsible for submitting the HREC progress report to the HREC. An additional Site Report/Closure Form (RGO) report must also be submitted by the SVHM PI.

Each site should also ensure that a copy of their annual progress report is forwarded to their local research governance office as per their local requirements.

All data extracted from the annual progress report will be recorded electronically via the database.

If the research is discontinued, a final report is required which details the circumstances surrounding the discontinuation, and a summary of progress. A final report must also be submitted on completion of the research.

File Audits

A minimum of 1 random file audits will also be conducted per month. An approved study will be randomly selected from the Research Governance Unit database. The Investigators will be notified via email that an audit will be performed, and that all files must be made available at a mutually convenient time. The RGU will conduct an audit, focusing on information specific to the documentation of participant consent, security of records, adherence to the approved protocol, and the quality of documentation/record keeping.

Serious Adverse Events

In addition, all serious adverse events must be reported as described within the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic good (2016), with local events to be reported within 24 hours of occurrence (or as soon as practicable). Periodic audits of SAE submission times will be undertaken, with reminders distributed to those who fail to adhere to the reporting timeframe.

Deviations and Violations

In the event that researcher or sponsor initiated monitoring activities reveal deviations from the approved protocol, or any conduct that affects the ethical acceptability of the study, the HREC must be notified in writing as soon as practicable. All notifications will be reviewed by the Research Governance Unit, Chair, and/or HREC as required.

Data Safety Monitoring Committees/Boards

All decisions made by Data Safety Monitoring Committees/Boards must be reported to the HREC in writing as soon as practicable.

Associated Procedures/Instructions

Procedure 5.26 – Safety Reporting

Reference Documents

- The National Statement on Ethical Conduct in Human Research (2023)
- Australian Code for the Responsible Conduct of Research (2018)
- NHMRC Safety monitoring and reporting in clinical trials involving therapeutic good (2016)

Authorised by: Dr Megan Robertson, Director of Research

Megan ROBERTSON (Jul 1, 2024 09:56 GMT+10)

Author: Alexandra Braun, HREC Executive Officer

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5.13 Monitoring Approved Research

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