HREC Standard Operating Procedure

5.23 Multisite Approval

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 5.5 of the National Statement on Ethical Conduct in Human Research (2023) by reducing the duplication of ethical review where possible.

Definitions

ERM is defined as the Ethical Review Manager, which is the database utilized by the multisite approval process.

Reviewing HREC is defined as the HREC who is allocated to undertake an ethical review of the study.

Accepting HREC is defined as other HRECs who accept the ethical approval of the reviewing HREC without further ethical review.

Lead Site is defined as the single site responsible for the ethical submission of documents for a study.

Master Participant Information and Consent Form is defined at the universal template which must be used by all sites participating in the study. This document must not contain site specific information.

Site Specific Participant Information and Consent Form is the template which must be used by all sites participating in the study and must be based on the universal Master Participant Information and Consent Form, modified to include site specific information (i.e. institution name, investigators name, contact details).

Procedures

The Streamlined Ethical Review Process for multisite clinical trials is an initiative of the Victorian, New South Wales, Queensland, Western Australia, Tasmania and South Australian Governments. This allows clinical trials to be reviewed by one HREC with the decision mutually accepted by other certified centres. This ensures that ethical review is sought once only and that each participating site need only obtain governance authorisation prior to the commencement of the study via the submission of a Site Specific Assessment (SSA).

SVHM is committed to this multisite approval process, and is certified to both review and accept the approval of other centres for multicentre trials. At all times, participating sites must adhere to the Standard Operating Procedures which are available from: https://www.health.vic.gov.au/sites/default/files/migrated/files/collections/research-and-reports/s/sops-for-research-governance-officers.pdf

The accredited HRECs which participate in the multisite approval pathway are listed in the Memorandum of Understanding, which can be accessed from the Victorian Department of Health website: https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0031/171976/Standard-Principles-for-Operation.-March-2024.pdf

HREC Review

The lead site or Sponsor is responsible for submitting the ethics application to the reviewing HREC.

For SVHM to provide ethical review, the following documents are required at the time of submission (electronic copies only):

Document
Fee Form
Human Research Ethics Application (HREA)
Victorian Specific Module
Participant Information Sheet and Consent Form (Master)
Investigator's Brochure (or Product Information)
Clinical Protocol
Budget
Questionnaires, Patient Facing Documents, etc.
Radiation Reports for each participating site
CV of Coordinating Principle Investigator (CPI)
CVs of all Site Principal Investigators (PI's)
CTN
HREC Review Only Indemnity
Insurance Certificate

If SVHM is listed as a site, the following documents are also required for governance review:

Document
Site Specific Assessment Form
Participant Information Sheet and Consent Form (Site Specific)
CV & GCPs of PI and AIs at SVHM
Clinical Trial Research Agreement/Research Collaboration Agreement (as applicable)
Standard Indemnity

Once a valid submission is received by the reviewing HREC, the submitter and/or Principal Investigator will be formally notified in writing to confirm the validity of the study and to confirm the meeting date at which the study will be reviewed. ERM will also be updated to ensure the study details are entered, to confirm the validity of the study, and to allocate the study to a meeting. The clock must commence running at this stage.

Once ethical review has occurred, the Principal Investigator will be formally notified of the outcome in writing. ERM must also be updated with the outcome, and the clock stopped.

Once the study has been ethically approved, a formal letter of approval must be sent to the Principal Investigator, listing the approved documents. This will be sent electronically, to allow the Principal Investigator to circulate the documents to the Sponsor (as applicable) Investigators at other participating sites, and the Research Governance Offices at each site where the study will be conducted.

Once approval is granted, other sites should commence the submission of SSA applications to other participating sites, using the approved documents as templates.

SSA Review

Once ethical approval has been obtained from an accredited HREC, a Site Specific Assessment application must be submitted by each participating site to their respective Research Governance Office, for governance review only.

SSA Applications must include the letter of approval from the lead site, all ethically approved documents, a site specific PICF and any legal documents including Clinical Trial Agreements, Insurance Certificates and CTN forms.

Once governance authorization has been granted, the site Principal Investigator will be notified in writing. ERM must also be updated to record the authorization.

Amendments

Where SVHM is the reviewing HREC, a full submission of the amendment is required for review and formal ethical approval. Once the amendment has been approved, a formal letter of approval must be sent to the Principal Investigator, listing the approved documents. This must be sent electronically.

Where SVHM is the accepting HREC, a full submission of the amendment along with the HREC approval letter is required for governance review. Once the amendment has been approved, a formal letter of approval must be sent to the site Principal Investigator.

Adverse Events
Where SVHM is the reviewing HREC, a full submission of any related, potentially related or possibly related Suspected Unexpected Serious Adverse Reaction (SUSAR) as well as line listings and annual safety reports are required for review and formal ethical approval.

Once the adverse event has been approved, a formal letter must be sent to the Principal Investigator. This must be sent electronically.

All adverse events occurring at SVHM must be reported to the HREC as soon as possible.

Where SVHM is the accepting HREC, only those adverse events occurring at SVHM or those that have an impact on the conduct of the trial must be reported as soon as possible.

Associated Procedures/Instructions

Procedure 5.13 – Monitoring Approved Research
Procedure 5.7 – Document and Record Management
Procedure 5.11 – Minimising Duplication of Ethical Review

Reference Documents

- The National Statement on Ethical Conduct in Human Research (2023)
- Australian Code for the Responsible Conduct of Research (2018)

Authorised by: Dr Megan Robertson, Director of Research

Megan ROBERTSON (Jul 1, 2024 10:07 GMT+10)

Author: Alexandra Braun, HREC Executive Officer

Date Issued: 2011

Date Revised: 2024 **Next Review:** 2027

5.23 Multisite Approval

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