Early Phase Clinical Trials – Human Research Ethics Review Procedure

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TARGET AUDIENCE and SETTING

Sponsors, Principal Investigators, and all staff conducting research at Monash Health, or research reviewed by Monash Health Human Research Ethics Committees (HREC).

PURPOSE

This procedure applies in the following instances:

- Monash Health is providing HREC Review Only for an early phase trial being conducted at another organisation;
- Monash Health is providing HREC Review for an early phase trial **and** is also providing Site Authorisation for the study to be conducted at Monash Health.

The Monash Health HREC composition adheres to the National Statement on Ethical Conduct in Human Research (NHMRC 2023), and early phase trials are reviewed in accordance with the National Statement on Ethical Conduct in Human Research (NHMRC 2023) and the Victorian Department of Health Early Phase Clinical Trials Guidance on the Scientific Expert Review Toolkit.

The HREC may seek the advice of an external or internal Scientific Expert Reviewer on any aspect of an early phase clinical trial application which is higher risk and may be beyond the expertise of its membership. Scientific Expert Review is intended to support and supplement quality and safety decision making in the HREC Review process (Coordinating Office for Clinical Trial Research 2023).

DEFINITIONS

Research: Includes at least investigation undertaken to gain knowledge and understanding or to train researchers.

Early phase trials: Broadly defined as non-therapeutic, exploratory trials in human participants who may be healthy volunteers or have a specific disease (for the purposes of this document, First Time in Human and Phase I trials).

HREC Review: Review of research by a Human Research Ethics Committee or other body.

Site Authorisation: Approval by an organisation to conduct research within that organisation. A HREC approval may be granted, however, before the research may commence, the organisations involved have a responsibility to ensure the quality, safety and ethical acceptability of the proposed research meets with their local capabilities and requirements.

VMIA: Victorian Managed Insurance Authority.

GMO: Is a genetically modified organism (GMO), such as a plant, animal or other organism that has been modified using gene technology, or an organism that has inherited modified traits from a GMO.

PRECAUTIONS/CONTRAINDICATIONS

Monash Health facilitates the conduct of Human Research in accordance with the Australian Code for the Responsible Conduct of Research (NHMRC 2018), The National Statement on Ethical Conduct in Human Research (NHRMC 2023), Australian and Victorian legislative requirements, and the Victorian Department of Health Early Phase Clinical Trials Guidance on the Scientific Expert Review Toolkit.

PROCEDURE

Monash Health has 3 pathways available for review of Research and Quality Assurance activities involving humans.

- HREC Review and Site Authorisation
  All Human Research will require review by the HREC and Site Authorisation to conduct the study at Monash Health. The submission requirements may be accessed at: https://monashhealth.org/research/.
- Site Authorisation
  Monash Health will accept the HREC Review from an organisation that is both certified by the National Health and Medical Research Council (NHMRC) under the National Certification Scheme, and is a Certified Reviewing HREC under the National Mutual Acceptance scheme. Site Authorisation is required prior to commencement of the study at Monash Health. The submission requirements may be accessed at: https://monashhealth.org/research/.
- Quality Assurance Registration Process (Exemption from HREC Review and Site Authorisation)
  Quality Assurance is an organised process that evaluates, assesses and seeks to improve health service delivery, to improve patient and population outcomes and health service efficiency. The registration requirements may be accessed at: https://monashhealth.org/research/.

All applications for HREC Review require the following documents:

- Completion of the Human Research Ethics Application form;
- Completion of the Victorian Specific Module;
- Protocol/Project Description;
- Participant Information and Consent Forms (NHMRC templates are preferred);
- Investigator's Brochure (only applicable for drug/device trials);
- Questionnaires/Advertisements/Participant Diaries;
- HREC Review Only Form of Indemnity (only applicable for commercially sponsored studies);
- Agreement for Ethical Review of Human Research Services (only if applicable for private organisations seeking HREC Review of a research study that is not commercially sponsored);
- Fee Form (only if applicable);

- Copy of the Institutional Biosafety Committee review and endorsement - this is only required if the application involves GMOs, gene therapy, or GMO-modified cell products. Please refer to the GMO and Gene Therapy Trials - Human Research Ethics Review & Site Authorisation/Governance for further information.

The submission requirements, submission deadlines and meeting dates may also be accessed at: https://monashhealth.org/research/.

Documents are submitted via the ERM website and upon submission the applicant must send an email to research@monashhealth.org with the ERM Reference Number and study title, to notify the Research Support Services team of the submission.

All research applications involving Monash Health as a site also require submission of a Site Specific Assessment (SSA) application for Site Authorisation via ERM. Upon submission the applicant must send an email to research@monashhealth.org with the ERM Reference Number and study title, to notify the Research Support Services team of the submission. The submission requirements may be accessed at: https://monashhealth.org/research/.

All early phase trial applications for HREC Review also require the following:

- Notification via email to research@monashhealth.org no less than 4 weeks prior to the advertised HREC submission deadline with the following information:
  - Title of study
  - Protocol summary
  - Name of Coordinating Principal Investigator
  - Participating sites and names of local Principal Investigators (for a multi-site study)
  - Study sponsor
- Submission of the full application no less than 2 weeks prior to advertised HREC submission deadline. The application must be uploaded on the ERM website and upon submission the applicant must send an email to research@monashhealth.org advising of the submission.
- The HREC may request the Coordinating Principal Investigator to advise of 3-4 potential Scientific Expert Reviewers, in the event the area of research is highly specialised.
- The HREC will seek a Scientific Expert Review and will request the reviewer completes:
  - Conflict of Interest – Declaration Form;
  - Deed of Acknowledgement of Obligations as an Expert Reviewer;
  - Relevant Review Proforma (Toxicology, Medicines, Medical Devices, Biologicals) and/or Supplementary Review Proforma (Biodynamics and Kinetics, Immunology);
  - In the event the Scientific Expert Reviewer is not an employee of a VMIA insured agency, the Scientific Expert Reviewer should provide Research Support Services with a Certificate of Currency for a professional indemnity insurance policy covering the provision of the service. If the Scientific Expert Reviewer does not have a current professional indemnity insurance policy or cannot provide information that their professional indemnity insurance policy covers them for the review, Research Support Services will complete the Coverage for Independent Reviewer Form and submit to the VMIA for approval.

- The Scientific Expert Reviewer's report will be presented to the HREC for consideration and if deemed appropriate by the HREC, a redacted copy will be provided to the Coordinating Principal Investigator, along with the HREC Review Outcome Letter.
- Upon receipt of the Scientific Expert Review, an honorarium of $1,000 (1,000 AUD) will be paid by Research Support Services directly to the Scientific Expert Reviewer.
- In the event the study is commercially sponsored, the HREC Review fee will incur an additional $1,000 (1,000 AUD) to the sponsor, to meet the cost of seeking an independent review.

REFERENCES

1. Coordinating Office for Clinical Trial Research (2023) *Early Phase Clinical Trials Guidance on the Scientific Expert Review Toolkit*, Victorian Government.
2. *Health Records Act 2001* (Vic).
3. National Health and Medical Research Council, Australian Research Council and Universities Australia (2018) *Australian Code for Responsible Conduct of Research*, Australian Government,.
4. National Health and Medical Research Council, *National Statement on Ethical Conduct in Human Research (2023)*, Australian Government.
5. OAIC (Office of the Australian Information Commissioner) (2023) *Australian Privacy Principles*, Australian Government, accessed 18 October 2023.
6. *Privacy and Data Protection Act 2014* (Vic).
7. Monash Health procedure on GMO and Gene Therapy Trials - Human Research Ethics Review & Site Authorisation/Governance.

Document Governance	
Supporting Policy	Human Research Strategic Policy
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