

# Early Phase Clinical Trials – Human Research Ethics Review Policy & Procedure

## TABLE OF CONTENTS

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[Target audience and Setting](#)

[Purpose](#)

[Definitions](#)

[Precautions/Contraindications](#)

[Procedure](#)

[References](#)

## TARGET AUDIENCE and SETTING

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All Monash Health staff and students conducting research on the campuses of Monash Health and the individual research institutes and groups for whom Monash Health is providing Human Research Ethics Review.

## PURPOSE

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This policy and procedure applies in the following instances:

- Monash Health is providing Human Research Ethics Review Only for an Early Phase trial being conducted at another organisation.
- Monash Health is providing Human Research Ethics Review for an Early Phase trial **and** is also providing Site Authorisation for the conduct of the study at Monash Health.

The Monash Health Human Research Ethics Committee composition adheres to the National Statement on Ethical Conduct in Human Research (NHMRC 2018) and early phase trials are reviewed in accordance with the National Statement on Ethical Conduct in Human Research (NHMRC 2018) and the Victorian Department of Health and Human Services 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' Committee members. Scientific Expert Review is intended to support and supplement quality and safety decision making in the ethics review process. (Victorian Department of Health and Human Services Early Phase Clinical Trials Guidance on the Scientific Expert Review Toolkit)

## DEFINITIONS

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**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 Studies and Phase I trials)

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

PROMPT Doc No: SNH0005788 v1.0		
Date loaded on PROMPT: 28/01/2020	Page 1 of 4	Review By: 31/07/2023
Version Changed: 28/01/2020	Document uncontrolled when downloaded.	Last Reviewed Date:

## Early Phase Clinical Trials – Human Research Ethics Review Policy & Procedure

**Low Risk Research:** Research in which the only foreseeable risk is one of discomfort.

**Site Authorisation:** Approval by an organisation to conduct research within an organisation. A Human Research Ethics approval may be granted. However, before the research may commence, the organisation/s involved have a responsibility to ensure the quality, safety and ethical acceptability of proposed research meets with their local capabilities and requirements.

**VMIA:** Victorian Managed Insurance Authority

### 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 2007 – Updated 2018), Australian and Victorian legislative requirements and the Victorian Department of Health and Human Services Early Phase Clinical Trials Guidance on the Scientific Expert Review Toolkit.

### PROCEDURE

Monash Health has 4 pathways available for Ethics Approval and Site Authorisation of Quality Assurance and Research activities involving humans.

- Quality Assurance Registration Process (Exemption from Ethics 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/>
- Low Risk Ethics Review and Site Authorisation. If a research study meets with the National Statement on Ethical Conduct in Human Research definition of low risk research, does not involve any of the participant groups exempt from low risk research or involve a waiver of consent, then the study may be considered for expedited review by the Low Risk Human Ethics Panel, a sub-Committee of the Human Research Ethics Committee.
- Human Research Ethics Committee Review and Site Authorisation. Human Research that is more than low risk will require review by the Human Research Ethics Committee 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 Ethical Review from an organisation that holds accreditation under the NHMRC Single Ethical Review Program and under National Mutual Acceptance of Single Ethical Review. An application for Site Authorisation is required prior to the conduct of the study at Monash Health. The submission requirements may be accessed at: <https://monashhealth.org/research/>

**All applications for submission for Human Research Ethics Review (both low and full ethics review) require the following documents:**

- Completion of the Human Research Ethics Application Form
- Completion the Victorian Specific Module

PROMPT Doc No: SNH0005788 v1.0		
Date loaded on PROMPT: 28/01/2020	Page 2 of 4	Review By: 31/07/2023
Version Changed: 28/01/2020	Document uncontrolled when downloaded.	Last Reviewed Date:

## Early Phase Clinical Trials – Human Research Ethics Review Policy & Procedure

- Protocol/Project Description
- Participant Information and Consent Forms (Department of Health and Human Services templates are preferred)
- Investigator’s Brochure (only applicable for drug/device trials)
- Questionnaires / Advertisements/ Participant Diaries
- HREC Review Form of Indemnity (only applicable for commercially sponsored studies)
- Agreement for Ethical Review of Research (only if applicable for external organisations seeking ethics review of a research study that is not commercially sponsored)
- Fee Form (only if applicable)

The submission requirements and submission dates may also be accessed at:

<https://monashhealth.org/research/>

Documents are submitted via the ERM website and upon submission a courtesy email is sent to [research@monashhealth.org](mailto:research@monashhealth.org) with the ERM Reference number and study title of the new submission.

All research applications involving Monash Health as a site also require an application for Site Authorisation via ERM and upon submission a courtesy email is sent to [research@monashhealth.org](mailto:research@monashhealth.org) with the ERM Reference number and study title of the new submission. The submission requirements may be accessed at: <https://monashhealth.org/research/>

**All early phase trial applications for submission for Human Research Ethics Review will also require the following:**

- Notification by the Chief Research Investigator via email to [research@monashhealth.org](mailto:research@monashhealth.org) no less than 4 weeks prior to the advertised HREC Submission date with the following information:
- Name of Chief Principal Investigator
- Title of Study
- Proposed sites and names of Principal Investigators
- Summary of proposed trial
- Study sponsor
- Submission of the application no less than 2 weeks prior to advertised HREC Submission date. The application must be uploaded on the ERM website and a courtesy email advising of the submission to [research@monashhealth.org](mailto:research@monashhealth.org)
- The HREC may request advice from the Chief Principal Investigator, of 3 -4 potential scientific expert reviewers, in the event the area of research is highly specialised
- The HREC will seek a Scientific Expert Reviewer and will request the reviewer completes:
- Conflict of Interest - Declaration Form
- Deed of Acknowledgement of Obligations as an Expert Reviewer
- in the event the Scientific Expert Reviewer is not an employee of a VMIA insured agency, the Scientific Expert Reviewer should provide the research office 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

PROMPT Doc No: SNH0005788 v1.0		
Date loaded on PROMPT: 28/01/2020	Page 3 of 4	Review By: 31/07/2023
Version Changed: 28/01/2020	Document uncontrolled when downloaded.	Last Reviewed Date:

## Early Phase Clinical Trials – Human Research Ethics Review Policy & Procedure

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.

- Relevant Review Scientific Review Proforma/s (Toxology, Medicines, Medical Devices, Biologicals) and/or a Supplementary Review Proforma (Biodynamics and Kenetics, Immunology)
- The written Scientific Expert Review report will be presented to the HREC for consideration and if deemed appropriate by the HREC, a de-identified copy will be provided to the Chief Principal Investigator, along with the HREC outcome on the review of the application.
- Upon receipt of the Scientific Expert Review, an honorarium of \$1000 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 \$1000 to the sponsor, to meet the cost of sourcing an independent review.

### REFERENCES

The National Statement on Ethical Conduct in Human Research (NHRMC 2007 – Updated 2018)

<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1>

Australian Code for the Responsible Conduct of Research (NHMRC 2018)

<https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018#block-views-block-file-attachments-content-block-1>

Health Privacy Principles: *Health Records Act* 2001:

<http://www.health.vic.gov.au/healthrecords/overview.htm>

Australian Privacy Principles:

<https://www.oaic.gov.au/privacy/australian-privacy-principles/>

Victorian Department of Health and Human Services Early Phase Clinical Trials Guidance on the Scientific Expert Review Toolkit

<https://www2.health.vic.gov.au/about/publications/policiesandguidelines/early-phase-clinical-trials-guidance-scientific-expert-review-toolkit>

Document Governance	
Supporting Policy	<a href="#">Clinical Ethics Committee (Operational)</a>
Executive Sponsor	Chief Medical Officer
Department Responsible	Clinical Research Department
Document Author	Deborah Dell, Manager Research Support Services & HREC
Consumer Review Yes or No	No

PROMPT Doc No: SNH0005788 v1.0		
Date loaded on PROMPT: 28/01/2020	Page 4 of 4	Review By: 31/07/2023
Version Changed: 28/01/2020	Document uncontrolled when downloaded.	Last Reviewed Date: