Low Risk Human Research Ethics Review and Site Authorisation Procedure

TARGET AUDIENCE and SETTING

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 Low Risk Human Research Ethics Review.

PURPOSE

This policy and procedure applies in the following instances, to assist researchers with understanding when an application requiring human ethics review may be eligible for Low Risk Ethics Review or require review by the full Human Research Ethics Committee.

- Monash Health is providing Human Research Ethics Review for low risk research being conducted at another organisation.
- Monash Health is providing Human Research Ethics Review for low risk research **and** is also providing Site Authorisation for the conduct of the study at Monash Health.
- Monash Health is accepting Human Research Ethics Review for low risk research from an organisation that holds both Certification under the NHMRC Single Ethics Review Process and Accreditation under then National Mutual Acceptance Scheme for Multi-site review **and** is providing Site Authorisation for the conduct of the study at Monash Health.

The National Statement on Ethical Conduct in Human Research defines low risk and negligible risk research as follows:

> *2.1.6 Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.*
>
> *2.1.7 Research is 'negligible risk' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.*

The National Statement on Ethical Conduct in Human Research on page 7 advises as follows 'When is ethics review needed?'

> *Institutions are responsible for establishing procedures for the ethical review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research (see Section 2: Themes in research ethics: risk and benefit, consent, and Chapter 5.2: Responsibilities of HRECs, other ethical review bodies, and researchers). Research with more than a low level of risk (as defined in paragraph 2.1.6,) must be reviewed by an HREC. Research involving no more than low risk may be reviewed under other processes described in paragraphs 5.1.18 to 5.1.21. Institutions may also determine that some human research is exempt from ethical review (see paragraphs 5.1.22 and 5.1.23)*

Further the National Statement on Ethical Conduct in Human Research advises on following situations which would require the proposed research be reviewed by a Human Research Ethics Committee.

> *5.1.6 The following types of research require review by a Human Research Ethics Committee (HREC):*
>
> *(a) all research that involves more than low risk;*

(b) research falling under the following chapters (except where research on collections of non-identifiable data under these chapters satisfies the conditions for exemption from review – see paragraphs 5.1.22 and 5.1.23):

• Chapter 4.1: Women who are pregnant and the human fetus

• Chapter 4.4: People highly dependent on medical care who may be unable to give consent

• Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness

• Chapter 4.7: Aboriginal and Torres Strait Islander Peoples and some categories of research falling under

• Chapter 4.6: People who may be involved in illegal activities (see first bolded paragraph for details).

5.1.7 For research that carries only low risk (see paragraph 2.1.6) and does not fall under any of the chapters listed in paragraph 5.1.6, institutions may choose to establish other levels of ethical review. These levels are described in paragraphs 5.1.18 to 5.1.21.

5.1.8 Research that carries only negligible risk (see paragraph 2.1.7) and meets the requirements of paragraphs 5.1.22 and 5.1.23 may be exempted from ethical review.

DEFINITIONS

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

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

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

Negligible Risk Research: Research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is of inconvenience only.

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.

PRECAUTIONS/CONTRAINDICATIONS

I 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) and Australian and Victorian legislative requirements.

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STANDARD REQUIREMENTS

When undertaking any clinical interaction with a patient, staff are expected to;

- Perform routine hand hygiene. Refer to the Hand Hygiene Procedure.
- Introduce themselves to the Patient and Carer/ Family if in attendance
- Check patient identification. Refer to the Patient Identification Procedure.
- Obtain consent as per the Consent to Medical Treatment Procedure.
- Document interaction in the electronic medical record or health record using black pen; including date, time, signature and designation.

PROCEDURE

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

1. 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/
2. 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.
3. 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/
4. 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
- 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 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 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 with the ERM Reference number and study title of the new submission. The submission requirements may be accessed at: https://monashhealth.org/research/

If the application is deemed to be suitable for low risk review, an expedited review will be conducted by the Low Risk Human Research Ethics Review Panel and written feedback will be provided within 12 – 14 days of the submission closing date. All low risk reviews are ratified by the Human Research Ethics Committee. If the application is deemed more than low risk, the application will be included in the Human Research Ethics Committee agenda. Written feedback is provided within 15 – 18 days of the HREC submission closing date (NB Days refer to actual days and not working days).

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/

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