

TARGET AUDIENCE and SETTING

All Monash Health staff and students conducting Quality Assurance/Negligible Risk Research on the campuses of Monash Health.

PURPOSE

Quality Assurance/Improvement (QA/QI) is an organised process that evaluates, assesses and seeks to improve an aspect of Monash Health’s health service delivery to our patients and community.

QA activities often involve the collection, use and disclosure of health, personal and sensitive information for the purpose of funding, management, planning, monitoring improvement or evaluation of health services. Common QA activities include sentinel event monitoring incident monitoring, root cause analysis, medical record review and clinical audit. QA activities may include activities involving staff, patients and members of the community.

The National Health and Medical Research Council document NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (March 2014) advises that regardless of whether an activity is called research or QA, those conducting the activity must consider whether the people involved will be exposed to any risk, burden, inconvenience or possible breach of their privacy.

Further, attempts to distinguish between whether an activity is research or QA can be unhelpful because one form of activity may evolve into another activity over time. Institutions are advised to develop policies around oversight of QA.

Many quality assurance and improvement activities can be managed locally and do not need to be registered with the Monash Research Support Services. This procedure does not apply in the following instances:

- The proposed Quality Assurance Activity will only involve Monash Health staff (including students on clinical placement at Monash Health).
- There is an existing departmental mechanism for oversight of Quality Assurance activities.
- There is no intention to present or publish the results in a forum External to Monash Health.

Monash Health will not grant Quality Assurance Registration/Human Research Ethics exemption for any organisations external to Monash Health. If the activity involves multiple organisations, then a separate application to each individual organisation will be required.

Please note that whilst there is a Victorian Quality Assurance (QA) Application Form available on the Ethical Review Manager website:

<https://au.forms.ethicalreviewmanager.com/Account/Login?ReturnUrl=%2fActivityForm%2fIndex> it is strongly advised that the applicant checks with the each organisation involved in the activity, prior to completion of the Form because some organisations may have an alternative pathway.

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.

PROMPT Doc No: SNH0135419 v3.0		
Date loaded on PROMPT: 24/09/2019	Page 1 of 4	Review By: 30/06/2024
Version Changed: 18/06/2021	Document uncontrolled when downloaded.	Last Reviewed Date: 18/06/2021

Quality Assurance Policy & Procedure

Procedure

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

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.

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](#).
- Keep the patient/carer informed and involve them in decision making.
- 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).
(Steps listed below in this section)
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. The submission requirements may be accessed at:
<https://monashhealth.org/research/>
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/>

PROMPT Doc No: SNH0135419 v3.0		
Date loaded on PROMPT: 24/09/2019	Page 2 of 4	Review By: 30/06/2024
Version Changed: 18/06/2021	Document uncontrolled when downloaded.	Last Reviewed Date: 18/06/2021

Registration of Quality Assurance:

Step 1 – Monash Health Employee completes the Victorian Quality Assurance (QA) Application Form online at:

<https://au.forms.ethicalreviewmanager.com/Account/Login?ReturnUrl=%2fActivityForm%2fIndex>

The Application Form is online and will request the names of the team, Head of Department Approval and a short project description/protocol.

Step 2 – Following completion of the Quality Assurance (QA) Application Form, Monash Health employee sends a courtesy email to research_qa@monashhealth.org advising:

- ERM Reference Number
- Project Title

Step 3: The Quality Assurance (QA) Application Form will be reviewed by the HREC Manager and if required a member of the Human Research Ethics Committee.

An email will be sent to the first named investigator within 3 working days. If the study is deemed to be QA and exempt from Human Research Ethics Review, a letter will be attached to the email, which may be used for verification purposes with journal editors/conference organisers if there is an intention to publish the results. The outcome will also be recorded on the Ethical Review Manager website.

If the activity is deemed to require human research ethics review, this advice will be communicated within 3 – 5 working days.

REFERENCES

The National Statement on Ethical Conduct in Human Research (NHRC 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 (NHRC 2018)

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

NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (March 2014)

https://web.archive.org/web/20170922112940/https://www.nhmrc.gov.au/files_nhmrc/publications/attachments/e111_ethical_considerations_in_quality_assurance_140326.pdf

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/>

QA Negligible Risk Information for Researchers

<https://au.forms.ethicalreviewmanager.com/Personalisation/DisplayPage/50>

KEYWORDS

QA, QI, retrospective audits

PROMPT Doc No: SNH0135419 v3.0		
Date loaded on PROMPT: 24/09/2019	Page 3 of 4	Review By: 30/06/2024
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