Mercy Health

Care first

Research Handbook

For Applicants

Last updated – 01 May 2025

This handbook is subject to revision.

The most recent version is available from the Mercy Health Research Website and Prompt

Contents

Purpose

The purpose of this handbook is to provide guidance to applicants in preparing and submitting a research application. Information is also provided regarding the process for quality assurance or audit activities, as well as ongoing requirements subsequent to any project approval. It outlines the specific expectations that need to be met to conduct such projects at Mercy Health, in accordance with Mercy Health mission and values, institutional policies and procedures, Catholic Health Australia Code of Ethics, state and national legislation, regulations, frameworks, guidelines and codes of practice.

What is research?

Research is the creation of new knowledge and/or the use of existing knowledge in a new and creative way to generate new concepts, methodologies, inventions and understandings (Australian Research Council).

Research with a rationale to provide new information that will inform or improve future practice is integral to Mercy Health's core business of health service provision, and forms part of our strategic framework. Well-designed research has a clear aim and research question(s), and is based on current knowledge of the research topic in relation to both the research site(s) and the wider community, incorporating a review of current literature. A sound research methodology will achieve the aim and answer the research question(s), providing new knowledge that may translate to improved practice. There is an expectation that ethical research is integrated into core functions of the organisation in order to fill knowledge gaps and contribute to continuous safety and quality improvement in health care provision.

Research is more than the collection of existing information. It seeks to answer questions such 'Is X procedure effective and safe?' or 'Is X procedure more effective and/or safer than Y procedure?' Research requires ethics and governance approval before it may start.

What is *not* research?

The collection of existing information alone, such as a retrospective review of records to complete an audit or Quality Assurance (QA) activity, does not constitute research. It is important to understand the difference, as the requirements and review process for these are different. Once given governance approval, an audit or QA activity may begin without needing to obtain ethics approval.

Quality Assurance and Audits

QA and audits seek to generate data that directly inform or improve the local clinical service. Clinicians and staff are encouraged to use existing data for QA activity (checking that standards and guidelines are being met and followed respectively) and auditing (review and planning purposes). Example appraisals are 'how many complications arose from procedure X over the last year', or a questionnaire asking about staff satisfaction *within* a health service. QA / Audit activities are therefore not considered research, as they are not seeking to generate new knowledge that is broadly generalisable across other clinical services. Proposals need to be submitted to confirm that they meet criteria for exemption of ethics review and so that they can be recorded on the hospital's central register of projects for reporting purposes. You can request confirmation of exemption from ethics review by submitting the Mercy Health QA and Audit Application form to RGO@mercy.com.au.

As long as personally identifiable data is not disclosed beyond treating clinicians or staff who routinely have access to the data (for management of care), there is no project specific patient consent required. This is because the clinical information is being appropriately used for the purpose for which the data is collected, as out lined in the Victorian Health Records Act, 2001.

If an activity goes beyond quality assurance or audit, such as comparing existing interventions or trialling something new, the project is considered research and the requirement for consent (or a justified waiver) applies. A research proposal needs to be submitted either as a Lower risk (no risk of harm), or Higher risk (risk of harm) application (see below).

Research risks

Risk is defined as potential for harm (high risk) or discomfort (low risk).

Harm may manifest in several ways:

- Physical harm - such as bodily injury, reduced physical ability, ailment, disease or death.
- Psychological harms – such as mental illness or negative emotional impact e.g. distress, fear, guilt or lowered self-esteem.
- Cultural harms – such as negative impacts relating to traditional beliefs or customs which may include misrepresentation or discrimination.
- Legal harms – such as discovery of criminal conduct which may impose a legal obligation on the discoverer to report such matters as domestic violence or abuse, etc.
- Social harms – such as unauthorised disclosure of personal information and negative impact on reputation and/or relationships, or a person's ability to gain employment or access insurance.

Some of these harms may extend to family members of the research participant and there may also be additional economic impacts.

Discomfort is less serious than harm and may also be psychological or physical. For example, mild anxiety triggered by an interview or focus group session, or minor unease induced by non-invasive tests, such as measuring blood pressure.

Even less serious than discomfort is **inconvenience**. Examples include time impost of completing an anonymous survey or travel required for participation in an on-site activity.

Some projects may have **no risk**. These include Quality Assurance (QA) activities that seek to confirm that guidelines and standards are being met, or retrospective audits with not patient contact and no disclosure of personally identifiable data beyond treating clinicians or staff who routinely have access to the data for management of care.

Mercy Health Research Governance and Ethics

The purpose of research governance is to ensure adequate risk mitigation measures are implemented. Considerations also include alignment with Mercy Health mission and values, resourcing, data security and whether regulatory and legal requirements are appropriately addressed.

Research ethics is one component of research governance and all research projects involving human participants must be reviewed and approved by a Human Research Ethics Committee (HREC) to ensure they will be conducted ethically, with scientific integrity and regard for the autonomy of individuals (or their medical decision maker) to make an informed decision about participation.

Both research ethics and governance of Mercy Health research projects are reviewed by St Vincent's Hospital Melbourne.

We know that there may be significant risks involved in carrying out research. Nonetheless, it plays a crucial role in the provision of evidence-based healthcare. Therefore, potential risks that are outweighed by potential benefit are considered acceptable as long as the risks are clearly explained to potential participants, and well managed. When designing your research project, it's important to consider the potential risks and clearly articulate appropriate risk mitigation measures in your research protocol so as to minimise the potential for harm to, not only research participants, but also their families, investigators, the institution and the wider community.

Guiding research governance principles are set out in established institutional, state and national ordinances listed at the beginning of the next section.

Conducting Research at Mercy Health - Start at the start

All intending investigators need to read this Handbook and familiarise themselves with relevant requirements and the process for research conduct at Mercy Health before embarking on research. Identify relevant industry standards and ensure compliance with legislation and guidance material from the list below:

- Australian Commission on Safety and Quality in Health Care: The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials, February 2022
- Australian Government: Privacy Act, 1988
- Australian Government Department of Health Therapeutic Goods Administration: Australian clinical trial handbook, August 2021
- Australian Institute of Aboriginal and Torres Strait Islander Studies: AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research 2020
- Australian Research Council: Research Integrity Policy, 1 July 2023
- Catholic Health Australia: Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (Chapter 6, *Research*)
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH): Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2) (Annotated with TGA comments)
- Mercy Health Research Governance Framework (Mercy Health employee access via Prompt)
- National Health and Medical Research Council, Australian Research Council and Universities Australia: Australian Code for the responsible Conduct of Research, 2018
- National Health and Medical Research Council, Australian Research Council: Ethical guidelines for research with Aboriginal and Torres Strait Islander peoples
- National Health and Medical Research Council, National Statement on Ethical Conduct in Human Research, 2023 (subsequently updated)
- Victorian Department of Health: Healthcare that counts: A framework for improving care for vulnerable children in Victorian health services
- Victorian Government: Health Records Act, 2001

Applying to conduct research

The Research Flowchart in **Figure 1** illustrates the proposal, review and ongoing governance process.

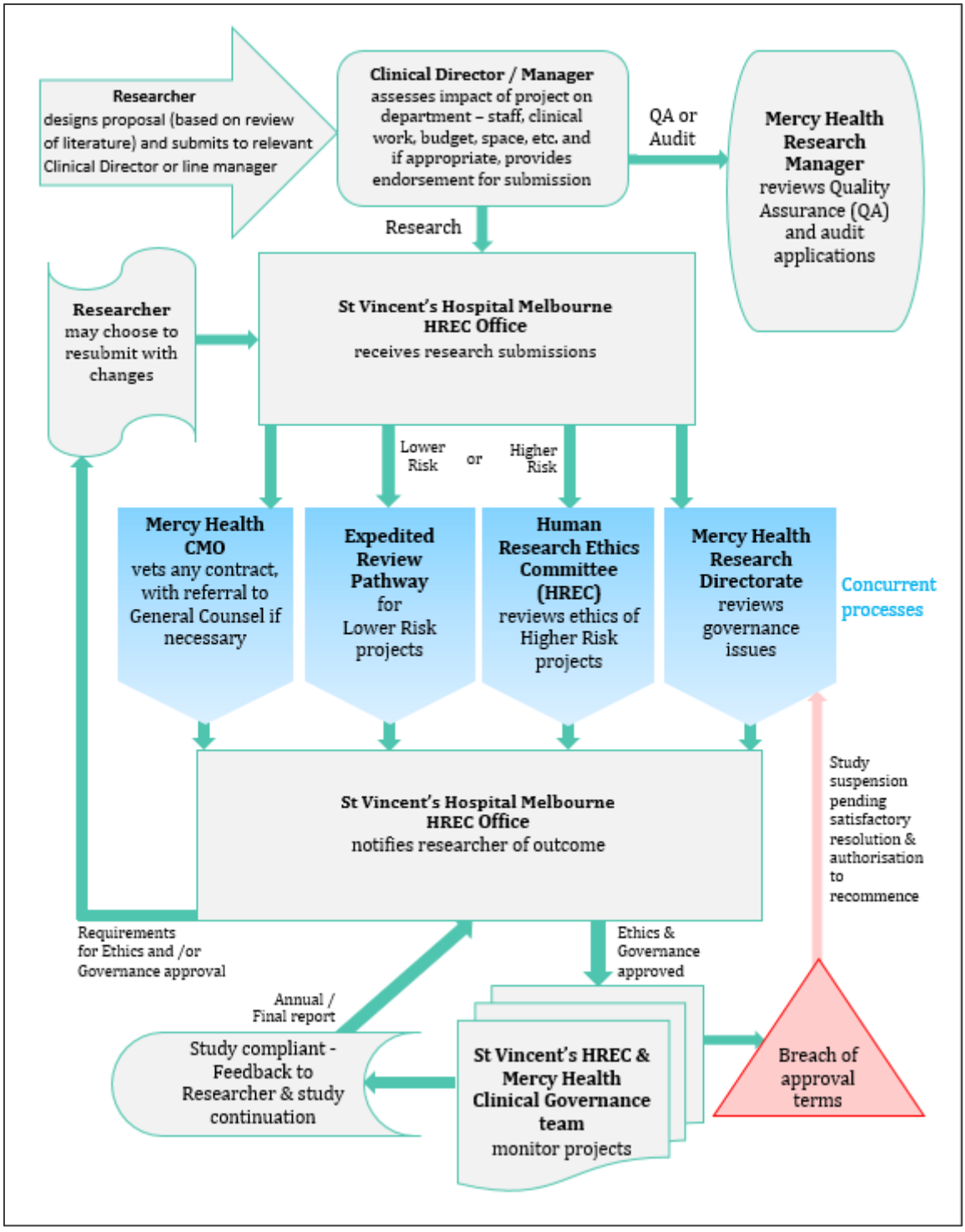

Figure 1: **Research flowchart**

Do I have the right training and qualifications?

Current **Good Clinical Practice (GCP)** certification and research integrity training is mandatory for all higher risk project investigators. Both are also strongly recommended for other members of the research team. GCP courses are widely available and certification will be accepted from any organisation, as long as it meets the internationally accepted standard [ICH E6 (R2) GCP]. Any Australian university Research Integrity training will be accepted.

One free online source of training is the Australian Clinical Trials Education Centre (A-CTEC). GCP training must be updated *every three years* to maintain current certification. Research integrity training only needs to be completed once.

Researchers and support staff are also encouraged to make use of the other excellent training resources available from A-CTEC, including *Trial Essentials for Investigators* and *Trial Essentials for Research Support Team*. These training modules have been developed based on a competency framework and address role-specific training needs in accordance with the *National Clinical Trials Governance Framework*.

How do I prepare a research application?

Once you have read this handbook and familiarised yourself with all the relevant ordinances that apply to your proposal, you need to develop your project protocol and, if you are a novice (student or not extensively published) researcher, have it reviewed by an experienced researcher in the subject field. Prepare participant information form(s) if needed (see ***Writing Information for Participants and Informed Consent*** below) and the relevant application form(s) along with any other project-specific documents.

Documents for submission:

- Project protocol*
- Advertising material*
- Participant information and consent form(s)*
- Questionnaires / surveys*
- Telephone / interview scripts*
- Letters to participants*
- Diaries / Data collection forms*
- Investigator's brochures* / product information*
- Project budget*
- Grant or funding confirmation
- Site-specific clinical trial governance documents
    - Clinical trial registration evidence (prior to recruitment)
    - Research agreement
    - Medicines Australia form of Indemnity (for commercially sponsored trials)
    - Insurance certificate
    - Application form(s) including endorsement signature from Divisional Director, Head of Department and any additional supporting Department.
    - Credentials for each Mercy Health investigator
        - CV
        - GCP certificate for each investigator
        - Research Integrity certificate for each investigator / support staff

**** All project-specific documents need to include a document name, version number and date in the footer to facilitate version control.***

Partnering with Consumers

When designing your project, think about the target population. Consumer representatives can provide a different and pertinent perspective which you may not otherwise consider. They can contribute insight into practicalities of implementation which can in turn improve recruitment rates and even the likelihood of effective translation of results into improved healthcare.

While everyone is a consumer, of sorts, a true consumer *representative* is linked to one or more consumer groups. They can act as a conduit between consumers and researchers, providing a rich source of valuable input into research design and analysis and they can also provide direct dissemination of results, meaning the target population receives information about current best practice relevant their situation as new developments arise, and are therefore empowered to seek the best care.

Partnering with consumer representatives is highly recommended, particularly in clinical trials, and may even be a prerequisite for grant funding. Assistance is available from the Mercy Health Consumer Liaison Office - clo@mercy.com.au. Additional resources are available from Safer Care Victoria.

Writing a Project Protocol

A project protocol needs to clearly describe all relevant components of the project:

Background and literature review
What is already known about the research topic in relation to the wider community and the specific site(s) to be studied?

Rationale
How might new information from the study inform / improve future practice?

Aims and research questions
What gaps in knowledge do you hope to fill?

Inclusion / exclusion criteria
What are the parameters for participant selection?

Recruitment and consenting procedures
How, when, where, and by whom will these tasks be performed? Note,

i. participants must have **opportunity to ask questions and seek advice from others** before providing consent. Refer to *National Statement* 2.2.4.
ii. An existing relationship between the investigator and potential participant may constitute a **power imbalance** e.g. doctor / patient, supervisor / subordinate, or teacher / student. If possible, an independent person should make the initial introduction of the project to avoid potential for coercion. Refer to *National Statement* 4.3.
iii. where making direct contact with patients / medical decision makers may cause distress or is difficult due to a significant lapse of time or other reason, a **waiver of consent** may be justified. Refer to *National Statement* 2.3.10.

Methods
How will the project be conducted? What data will be collected? A flow chart may be helpful.

Risks and Benefits
Consider all possible outcomes or repercussions for participants and the wider community

Cohorts and randomisation procedures
If you wish to compare one intervention to another or to a placebo or no intervention, how will participants be allocated to different groups?

Collection, use, storage and disposal of data (including samples)
How, when, where, and by whom will these tasks be performed? How long will data be kept? Who will have access? Note, REDCap is the approved platform for secure storage of electronic data.

Confidentiality
Use the following terms to describe how data / samples will be identified / labelled at each stage of the project:

- Identifiable e.g. name, UR or date of birth
- Re-identifiable e.g. using a unique study identification code which only specified study personnel are able to link back to the participant – specify how the 're-identification key' will be stored and who will have access.
- Non- identifiable – no possible way of linking back to the participant

Statistical analysis

How will the data be analysed to answer the research question(s)?

Distribution of results

How do you plan to report, present or publish results?

To avoid delay in project approval, ensure that the research protocol clearly addresses all of the above aspects when first submitted. Any gaps in this information will delay approval.

Writing information for Participants and Informed Consent

All research projects involving human participants must include a process for obtaining informed consent, including projects where data is collected directly from patient records for analysis, unless a ***waiver of consent*** is justified (refer to National Statement 2.3.10). Potential research participants need to be provided with adequate information about the research so that they are able to make an informed decision about whether or not they wish to participate. Include details about the purpose of the project, what is expected of participants, including time impost for any tests, procedures, surveys, etc., potential risks and benefits, what data will be collected and how they may obtain results of the project.

Types of Consent

Consent may be **specific** (for the current project only), **extended** (for the current and future *related* projects, or **unspecified** (for current and any future research. If you wish to use the data collected beyond the current project, provision needs to be made for the participant to choose their level of consent, if possible, i.e. by providing check boxes to select either specific, extended or unspecified consent on the consent form. If the project protocol requires that participant data will be used for future research, participants need to be informed that, by consenting, they agree to their data being used in future research.

Consent also may be **implied** by participation. Note, if participant involvement comprises no more than completion of a survey or interview, it may be preferable to provide a participant information sheet without a consent form. This may allow participants to remain anonymous and can be particularly effective in boosting recruitment if participants prefer not to have their personally identifiable details recorded.

Waiver of Consent

In most cases, this requires specific consent from the individual to whom the information relates, or their authorised representative. If obtaining consent is not possible or may cause distress, a waiver of consent may be applied for. You must provide adequate justification for a waiver of consent to be granted by appropriately addressing National Statement 2.3.10 (a) to (i).

Appropriate language

Information needs to be presented in plain language. If medical or technical words have to be used, explain them in lay terms (school year 8 level) in the first instance. Similarly, acronyms must follow full wording in the first instance.

Be succinct. Use subheadings and punctuation appropriately. Short sentences and paragraphs are easier to comprehend than long convoluted wording. Ensure that everything within a subheading is relevant to that subheading. Provide all and *only* relevant information. Avoid repetition. By using subheadings, you can refer back to earlier statements rather than repeat them. If you need to mention a list of four or more, it is best to use dot points, rather than a long sentence. This and other formatting techniques (e.g. indenting subsections and italics for emphasis) can aid clarity when used appropriately.

State facts using neutral language and avoid phrases that may be considered coercive. For example, instead of ‘this is an important study’ make statements like ‘the results of this study will help researchers understand…’, ‘…will inform future research’, ‘…will aid planning for…’, ‘…may lead to improved treatment of…’ etc..

Personal Data Privacy

Data held in Victorian medical records are protected by the Victorian *Health Records Act 2001*. Within Australia, access, use and disclosure of personal health information for research purposes must also align with the *Australian Privacy Principles*. If identifiable or re-identifiable participant data is to be sent overseas, participants need to be informed of where their data will be sent, and, that privacy laws outside of Australia may be less stringent than Australian privacy laws.

Contact for Complaints

Any complaints are to be directed to a trained and dedicated Consumer Liaison Officer (not the Ethics Office). Provide the following contact details under a Complaints heading –

Consumer Liaison Officer
Telephone: (03) 8416 77 83
Email: Feedback@mercy.com.au

Participant Information and Consent Form Templates

Participant Information and Consent Forms (PICF) templates are available from the Victorian State Government website. Choose the template that best suits your type of project and tailor each relevant section to your project. Only delete sections if they are not applicable to your project. Ensure that you remove all template instructions and text boxes, edit the footer to include appropriate document naming, version number and date, include Mercy Health investigator contact details, and the Mercy Health logo.

Payment of participants in research

It is appropriate to offer participants reimbursement for direct 'out of pocket' expenses (such as travel expenses). Researchers are encouraged to consider such reimbursement when planning clinical studies. Reimbursement should be structured so as not to induce participation. Refer to *National Statement* 2.2.10.

It is equally important that lack of reimbursement not exclude patients from participation in research.

If you intend to pay participants, you need to explain:

- the rationale for proposed payments
- how prospective participants will be advised of the provision of payments
- the method and timing of payments

Refer to the NHMRC's 2019 publication ***Payment of participants in research: information for researchers, HRECS and other ethics review bodies***

What form(s) do I need to complete and who will review my application?

The application form(s) required will depend on the level of risk. Consider the potential risks associated with your project and decide which of the following three category you think it fits into. If you think your project may fall into the Higher Risk category, start at the appropriate pathway. Trying to retrofit your project into a lower risk category will lead to unnecessary delay as you will be re-directed to complete appropriate forms for review.

Minimal or no risk

If your project is an internal audit or quality assurance (QA) activity to be performed by a person(s) who routinely have access to the required data and identifiable data will not be disclosed beyond this, it is likely to be of minimal or no risk. These projects may be exempt from ethics review, but still require governance review.

The Mercy Health Research Directorate keeps a central register of all projects. This enables the hospital to demonstrate that it is meeting the Commission on Safety and Quality in Health Care requirements for continued safety and quality improvements, as part of ongoing hospital accreditation.

Submit the Mercy Health QA and Audit Application form to RGO@mercy.com.au. You will be notified if there are any specific governance requirements and, once these have been met, you will receive confirmation of approval and may start.

Lower Risk

If your proposal involves research where the only foreseeable risk is one of discomfort, it will be considered as low risk. You will need to complete a low risk Human Research Ethics Application (HREA) form via the Ethics Review Manager (ERM) platform. The Site-Specific Assessment (SSA) form and Victorian Specific Module (VSM) can also be completed on ERM. Saved all forms as PDFs and submit along with all related project documents (see ***Preparing a research application*** above) via SAGE on the St Vincent's website.

Note, projects specifically targeting the following vulnerable populations should not be submitted as low risk, as they require full HREC review:

- Pregnant women & human foetus (except for non-sensitive surveys, epidemiology studies using non-identified data and the like)
- Children & young people (under 18) (except for epidemiology studies using non-identified data)
- People in dependent or unequal relationships (i.e. doctors/patients, employers/employees)
- People highly dependent on medical care unable to give consent
- People with a cognitive impairment, intellectual disability or a mental illness
- People who may be involved in illegal activities
- Aboriginal & Torres Strait Islander People
- People in other countries

Incidental inclusion of participants from the above categories is permitted in a low risk application.

Once all necessary documentation has been submitted, your application will be reviewed out of session (no submission deadlines). You will be notified of any requirements.

You must receive ethics approval **and** governance approval before you commence your project.

Higher Risk

Projects that have the potential to cause harm are higher risk. This includes surveys or interviews seeking sensitive or personally identifiable health information, projects targeting vulnerable populations (as listed above), and trials of a drug, device or other potentially harmful intervention.

If your proposal poses higher risk, you will need to complete a high risk Human Research Ethics Application (HREA) form and Site Specific Assessment (SSA) form via Ethics Review Manager (ERM), as well as a Victorian Specific Module (VSM), and submit along with all related project documents (see ***Preparing a research application*** above).

Higher risk research must undergo ethics review by an HREC. The St Vincent's HREC will assess the proposal in terms of research merit and integrity, justice, beneficence and respect, with regard for protecting the interests of participants, researchers, the institution and the wider community. Governance review will be undertaken by the St Vincent's and Mercy Health to assess any direct impact on the institution and its resources, ensure all regulatory obligations are met and ensure risk mitigation measures are adequate. Refer to the next section for further details regarding governance requirements.

You will be notified of any requirements.

You must receive ethics approval **and** governance approval before you commence your project.

Governance Review

Projects with approval from an external, HREC, must undergo local governance review and approval, via St Vincent's before commencement at Mercy Health.

Governance review is administered by the process of site-specific assessment (SSA) and can be conducted in parallel with ethics review.

Documents for governance submission:

- Site Specific Assessment form
- All relevant application documents as submitted and approved by the reviewing HREC
- corresponding HREC approval(s)
- Victorian Specific Module (VSM) if the HREC approval is from outside Victoria (to address differences in state legislation)
- CV for any local investigators who have not previously submitted
- GCP certificate for all clinical trials and higher risk project investigators
- Research Integrity certificate for all clinical trials and higher risk project investigators
- Mercy Health specific participant documents including the Mercy Health logo and contact details. Note, complaints need to be directed to:

  Mercy Health Consumer Liaison Officer,
  Ph. 03) 416 7783,
  email: feedback@mercy.com.au.

All projects need to meet the following governance requirements:

- compliance with governing frameworks, legislation, regulations, guidelines, codes of practice and institutional policies and procedures, including registration of any clinical trial seeking to test a drug or device to prevent, treat, manage or detect a medical condition prior to recruiting the first participant.
- credentialing, including provision of adequate training and appropriate certification of all investigators and research staff (see above)
- adequate resourcing, confirmed by sign-off from supporting department(s) e.g. Pharmacy, Pathology, etc., approved budget and allocation of staff, materials and space needed for the project
- endorsement from any Head of Department / Unit or external organisation that may be directly impacted by conduct of the project (even if they are not providing resources). This includes your direct line supervisor. Clinical research requires sign-off by the Head of Department / Unit. If the head is one of the researchers, endorsement needs to come from the administrator whom the head reports to. Evidence of endorsement from head of any supporting department e.g. Pharmacy, Pathology, etc. must also be provided. Endorsements may be provided either by signature on the application form or via Mercy Health email.
- ensuring research is conducted in accordance with the terms of ethics approval
- appropriately managed legal matters, including financial arrangements, risk mitigation, intellectual property and responsibilities of the contracting parties, via the following applicable documents:
  - **Clinical Trial Research Agreement (CTRA)** - required when Mercy Health is providing resources for an externally sponsored project, or **Research Collaboration Agreement (RCA)** - required when Mercy Health is providing resources for a collaborative study. Use the standard template available from the Medicines Australia website.
  - **Data Transfer Agreement (DTA)** - required for transfer of data from Mercy Health to an external party, or vice versa, where no additional resources are needed and details are not set out in a CTRA or RCA

- **Material Transfer Agreement (MTA)** – required for transfer of biospecimens from Mercy Health to an external party, or vice versa, where details are not set out in a CTRA or RCA
- **Insurance** – required for any interventional Greater than Low Risk clinical trial. Note, this may be provided by a commercial or university sponsor.
- **Form of Indemnity** - required for a commercially sponsored clinical trial. Use the standard template available from the Medicines Australia website.

Identifying Potential Participants and Recruitment

Hospital records must not be searched to identify individual patients who qualify for inclusion or to obtain personal contact details. Acceptable methods of identifying potential research participants and recruitment include seeking referral from treating clinicians, advertising, and approaching patients in person under acceptable (ethics approved) circumstances. All methods of recruitment must be detailed in the research protocol for HREC approval.

Data management

Where possible, data should be collected without identifiers. Any research data collected should adhere to the following:

- Hard copy data should be stored onsite in a locked office in a locked cabinet (or fridge for tissue samples).
- Electronic data should be stored in an encrypted file on a password protected non-portable computer, only accessible by an approved member of the research team.
- All data should be stripped of its identifiers and assigned a unique code that prohibits re-identification, other than by the approved project researchers if necessary.
- The re-identification key file that matches the unique participant codes with identifiers must also be encrypted and stored separately to the location of the source data and be accessible only to the approved project researchers.
- All data must be stored on Australian servers that adhere to Australian privacy laws, unless participants have provided informed consented to their data being sent outside Australia where privacy laws may be less stringent.
- Any data to be sent off-site must be in de-identified format (re-identifiable by local researchers only) and used only for HREC approved purposes.
- Data sharing arrangements and parameters of data use must be outlined in a Data Transfer Agreement (DTA) or Research Collaboration Agreement (RCA), or Clinical Trial Research Agreement (CTRA) and commit the parties to lawful, HREC-approved treatment of the data.

REDCap (Research Electronic Data Capture) is a free, secure, web-based application designed to support data capture for research studies. REDCap provides user friendly web-based case report forms, real time data entry validation and audit trails. More details are available in the REDCap Informational videos.

To access the REDCap software at Mercy Health, follow the REDCap Access and Use for Research Procedure available on Prompt.

Sponsorship of Clinical Trials

Sponsors may be internal or external. Mercy Health may provide research sponsorship in clinical trials comparing standard practices. This needs approval from the Research Governance Sub-Committee. Sponsors of trials involving novel therapies or devices include universities, research institutes, or commercial entities such as pharmaceutical, device or technology companies. Risks and liability associated with clinical trials are the responsibility of the sponsor. They need to seek insurance against such liability. Commercial sponsors must provide indemnification of liability to Mercy Health using the Medicines Australia Indemnity form. Sponsors regularly review results and make decisions

regarding the ongoing safety and feasibility of a trial (via a Data Safety and Monitoring Committee, if necessary). Clinical trials must have a nominated sponsor willing to fulfil these responsibilities.

Registration of Clinical Trials

Clinical trials must be publicly registered on a World Health Organisation (WHO) Registry Network platform such as Australia New Zealand Clinical Trials Registry (ANZCTR). Provide evidence of registration once completed. Evidence that the trial is publicly registered on a primary registry must be provided prior to enrolment of the first patient. Note, confirmation of ANZCTR registration may take up to eight weeks, so applicants need to allow ample time prior to commencing recruitment.

Where a clinical trial is testing a drug or device to prevent, treat, manage or detect a medical condition, it must also be registered on the Therapeutic Goods Administration (TGA) register through the Clinical Trial Notification (CTN) scheme or Clinical Trial Approval (CTA) scheme.

How do I submit an application and what happens after submission?

Complete all research application forms on the ERM platform and save as PDF files.

All research projects must be submitted for review via SAGE on the St Vincent's website and granted both ethics and governance approval before commencement. Refer to the **St Vincent's website** for detailed instructions.

The St Vincent's Research Governance Unit receives all project submissions and directs them to the applicable review pathway according to the initial assessment of risk. The final assessment of risk is the domain of the St Vincent's and Mercy Health Research Governance Offices, *not* the investigator.

The St Vincent's HREC meets fortnightly and you can expect a response with 10 business days. Turn-around for lower risk applications is 5-7 business days. The review and approval process can take longer, depending on the complexity and quality of the submission. You need to allow for this when planning your project.

You can minimize the time to approval by following these tips:

- **Use plain, clear and concise language throughout**
- **Include a literature review and justify your research**
- **Address any ethical consideration transparently**
- **Include the Mercy Health logo on all patient facing documents**
- **Ensure all project documents include a title, version number and date in the footer**
- **Submit all necessary documentation at once**
- **Don't delay submission for signatures, but do submit these as soon as they are available**
- **Proof read your application before submission**

Post Approval

Your approval letters will outline your responsibilities and ongoing compliance requirements.

Training renewal and keeping up with changes

Research requirements change to keep pace with the dynamic regulatory environment. It is essential that researchers stay abreast of any changes by keeping up with regular training and certification renewals. GCP training must be renewed every three years to stay current. A-CTEC provides training modules, access to webinars, action scenarios and communities of practice where you can share information and ask questions of counterparts across organisations.

Progress Reporting

An annual progress report must be submitted in accordance with the minimum reporting requirements of the National Health and Medical Research Council, and is due on the anniversary of the project approval date, for projects previously approved by Mercy Health HREC. Once transitioned to St Vincent's for research ethics and governance oversight, all progress reports will be due 1st of May each year.

All progress reports for projects approved by St Vincent's will be due on the 1st of May each year.

Once a project has been completed, a final report must be submitted, including any resulting publications.

Submit progress reports for Mercy Health approved projects to RGO@mercy.com.au using the Mercy Health progress report form.

Submit progress reports for St Vincent's approved projects to St Vincent's via SAGE. Further details on how to submit are available on the St Vincent's website.

Amendments

In most cases, amendment to an approved project protocol or any associated documents requires approval before implementation. For projects previously approved by Mercy Health HREC, download and complete the amendment request form and submit with any revised documents to RGO@mercy.com.au.

If a protocol change is required for safety reasons, this may be implemented immediately and reported via Mercy Health RiskMan. Follow-up with amendment submission for confirmation of approval.

To facilitate review, all changes to previously approved documents must be shown using 'tracked changes' i.e. underlining for additions and ~~strikethrough~~ for deletions. Revised documents must include an updated version number and date in the footer. Both 'tracked' and 'clean' copies must be submitted for review.

Reporting Adverse Events or Serious Adverse Events

You must report any Adverse Events (AEs) or Serious Adverse Events (SAEs). Complete the report form available from the Victorian State Government website and submit via RiskMan.

In line with the National Clinical Trials Governance Framework, integration of clinical trials reporting into hospital clinical governance processes, regardless of whether the incident is attributable to the trial intervention or not is mandatory.

Reporting protocol breaches

Even with the best of intentions, sometimes, mistakes can happen. It's important that any protocol deviations or violations are reported as soon as you become aware of them. Complete the report form available from the Victorian State Government website.The report needs to explain what happened, action taken and procedures that have been implemented to prevent a repeat occurrence.

Submit incident reports for Mercy Health approved projects to RGO@mercy.com.au.

Submit incident reports for St Vincent's approved projects to St Vincent's via SAGE. Further details on how to submit are available on the St Vincent's website.

Additional Resources

- Australian Clinical Trials Education Centre (A-CTEC)
- Austin Library (available to Mercy Health employees)
- Prompt (available to Mercy Health employees)
- REDCap

- Mercy Health Research Directorate – for general enquiries:
  email: RGO@mercy.com.au, or
  phone: 8458 4808.