Western Health

Research, Ethics and Governance

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This document is relevant to practice at all WH sites, EXCEPT Bacchus Marsh and Melton at this stage

Contents

1. Overview

Western Health recognises the importance of research to the provision of high-quality healthcare. It is committed to ensuring that research activities, including clinical trials, are conducted according to best practice guidelines and legislative responsibilities, and that the welfare and rights of all research participants are respected and protected. This also applies to the researchers and the institution.

Obtaining research ethics approval helps to ensure that the research is carried out professionally and considers relevant legal, ethical, organisational, and cultural standards. Governance authorisation addresses protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management and monitoring arrangements, and promotes good research culture and practice.

2. Applicability

This procedure applies to all Western Health employees, agents of Western Health (including persons with honorary appointments, university partners, visitors, and students), and any entity conducting research on its behalf or on Western Health patients, their data, and/or samples, staff and/or other resources. All collaborative research projects in which Western Health is involved must also comply with this procedure.

3. Responsibility

Individuals or groups undertaking research within Western Health are accountable to the Western Health Board of Management, under the Western Health Governance structure. The Western Health Board of Management is accountable to the Minister of Health, who is the community's elected representative.

The Western Health Board of Management is accountable for maintaining, via the Western Health Executive Team, an Office for Research (that provides direction and leadership in relation to research matters, undertakes monitoring and auditing activities, liaises with relevant Research and Ethics and Governance committees, encourages learning about and participation in research activities among all staff and reports the outcomes of research at the Health Service level.

The Executive Team, Divisional Directors and Clinical Services Directors are responsible for working with the Office for Research to ensure that, where appropriate, systems are in place to promote and monitor research activities within Divisions.

All Managers are responsible for ensuring that relevant staff receives education, training, or experience necessary to implement the requirements of this procedure.

All Directors of Departments in receipt of any NHMRC grant funding supporting health and medical research are responsible for ensuring that the funds awarded, and any interest accrued from these funds, are used and managed as per the corresponding approved Deed of Agreement.

Western Health Office for Research (Directors, Manager, Research Governance Officers, and Ethics and Governance Administrative Officers) are responsible for the ethical and governance review of research projects being undertaken across Western Health, and ongoing monitoring of approved projects and are also responsible for ensuring the overall efficient and effective coordination of research governance applications, procedures, and processes.

It is the responsibility of staff in supervisory positions to ensure that staff, trainees, and students involved in research projects at Western Health have the appropriate education, training, experience, mentoring, and support to conduct quality research, safely and responsibly.

Researchers (all Western Health staff and affiliates, including interns and students, who are involved in research associated with the Western Health) are responsible for undertaking research across Western Health in a safe and ethical manner, in compliance with all relevant policies, guidelines and procedures. Researchers should:

- Conduct research in compliance with NHMRC guidelines, Western Health policy, and requirements and all relevant laws and guidelines.
- Discuss all research projects and proposed research grant applications with, and obtain support from, the appropriate Clinical Director or Department Head.

- Obtain all approvals required to conduct the research project, including ethical and Western Health site specific research governance authorisation, prior to commencement of the research project.
- Be aware of, and adhere to, ethical principles of integrity, respect for persons, justice, beneficence, and veracity.
- Ensure that personal ambition and expectation of economic gain or material advantage must not compromise ethical, societal or scholarly considerations.
- Contribute to the monitoring of research by Western Health through processes, which include provision of regular reports as required by the institution, and through the prompt notification of adverse or untoward events.
- Ensure that the evidence of participation (participant information and consent forms and relevant visit data) are included in the participants' medical record, relevant information should be communicated to other clinical teams where the trial intervention has clinical implications.
- In addition to the researcher responsibilities outlined in the Western Health Researcher Code of Conduct, all Western Health staff and affiliates, including students, who are involved in research associated with the Western Health should:
- Conduct research safely.
- Adhere with ethical standards.
- Respect the dignity, privacy and cultural differences of human participants, animals used in research, the environment, and avoid harming them.
- Participate in ongoing training programs including in research integrity.
- Provide mentoring, training, and support of fellow researchers including new researchers.
- Be aware of, and appropriately manage, actual or potential conflicts of interest, whether financial or non-financial. This will generally require open disclosure and discussion, with the involvement of supervisors, managers, and colleagues.
- Employ appropriate methods and use a high level of rigour and objectivity in research activities.
- Manage research data responsibly including making and securely storing complete, clear, attributable, accurate, and enduring records of all research. Confidentiality must be observed for data of a confidential nature, for example from individual patient records. Secrecy may be necessary for a limited period in the case of research with commercial interest.
- Interpret results cautiously. In general, research results and methods should be open to scrutiny by colleagues within Western Health and through appropriate publications and conference presentation, to the wider scientific profession.
- Share findings and data openly, honestly, and promptly, as soon as they have established provenance, ownership claims and if there are any barriers to sharing the data such as legal requirements of contracts, intellectual property claims, or the uniqueness of the data may lead to privacy issues.
- Appropriately cite and, where applicable, obtain permission for the use of all published and unpublished work.
- Acknowledge in research outputs all contributors and contributions to the research described in the research output.
- Be listed as an author of a research output only when they have made a significant intellectual or scholarly contribution that they are willing to be accountable for and agree to be listed as an author.
- Participate in the peer review process. Give fair, prompt, and rigorous evaluations, and respect confidentiality when participating in peer review.

- Respect Aboriginal and Torres Strait Islander heritage in ways that promote Aboriginal and Torres Strait Islander cultures and understanding and respect between indigenous and non-indigenous Australians in the conduct of research in Australia.
- Provide complete and accurate information in all research applications including ethical, governance and funding applications and related documents.
- Use funds for research in accordance with relevant funding agreements.
- Ensure future use of research results are in accordance with applicable requirements and permissions.

Seek advice and discuss any concerns about the conduct of research with research integrity advisers and report any suspected research misconduct.

4. Authority

Research Program Director and Chief Medical Officer

5. Associated Documentation

In support of this procedure, the following Manuals, Policies, Instructions and/or Guidelines apply:

Name

Information Privacy

Record Keeping

Intellectual Property and Moral Rights

Research, Ethics and Governance Policy

Data Management in Research

Honorary Appointments

Conflict of Interest

Aboriginal and Torres Strait Peoples Recruited into Research Procedure

Consumer Feedback Management Policy

Consumer Feedback Management Procedure

Western Health Clinical Trial Governance Framework

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

NHMRC National Statement on Ethical Conduct in Human Research (2007 updated 2018)

National Clinical Trials Governance Framework

National Safety and Quality Health Service (NSQHS) Standards

Western Health Research Code of Conduct 2023

Western Health Office for Research – Information on procedures and processes for ethical and governance review of research, Research Agreements, Honorary Researcher Appointments

Western Health Standard Operating Procedures – Good Clinical Practice (GCP)

Western Health Standard Operating Procedures – Communication with HREC, Trial Sponsor and Insurer

Western Health Standard Operating Procedures – TGA Notification and Safety Reporting

Aboriginal Health Cultural Safety Plan 2022-2025

6. Credentialing Requirements

NIL

7. Definitions and Abbreviations

7.1 Definitions

For purposes of this procedure, unless otherwise stated, the following definitions shall apply:

Human Research Ethics Committee (HREC)	A committee established in accordance with the National Statement on Ethical Conduct in Human Research 2007 and updates, whose purpose is to review and approve projects involving human participants. The primary role of an HREC is to protect the welfare and rights of participants in research and to promote ethically good human research. Each member of a HREC is responsible for deciding whether, in his or her judgement, a proposal submitted to the HREC meets the requirements of the NHMRC National Statement and is ethically acceptable.
Low Risk Ethics Panel (LREP)	A body which reviews low & negligible risk research proposals involving human participants and their data to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. The National Statement (2007 and updates) requires that all research proposals involving human participants be reviewed and approved by an ethics committee.
National Statement	National Statement on Ethical Conduct in Human Research 2007. This has been jointly developed by the National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellor's Committee. The purpose of the National Statement is to promote ethically good human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community. The National Statement clarifies the responsibilities of: (i) institutions and researchers for the ethical design, conduct and dissemination of results of human research; and (ii) review bodies in the ethical review of research.
Participants	People who take part in research whether directly or indirectly (e.g. through the use of their information or stored tissue samples).
Consumer	A person who has used, or may potentially use the Western Health service, or is a carer for a patient using the Western Health services. A healthcare consumer may also act as a consumer representative, to provide a consumer perspective, contribute consumer experiences, advocate for the interests of current and potential health service users, and take part in decision-making processes.
Quality Assurance	An activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation).
Research	Is the systematic collection of information to test a hypothesis; a planned study of existing practices with a view to changing or improving practice in light of the study's findings and/or to increase understanding or the administration and analysis of data in response to surveys, interviews, questionnaires or opinion polling. Research includes scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research. Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through: taking part in surveys, interviews or focus groups; undergoing psychological, physiological or medical testing or treatment; being observed by researchers; researchers having access to their personal documents or other materials; the collection and use of their body organs, tissues or fluids (e.g. skin, blood, urine, saliva, and head, bones, tumour and other biopsy specimens) or their exhaled breath; access to their identifiable information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.
Researcher	Anyone undertaking research activities as defined above.
Principal Investigator	The person responsible, individually or as a leader of the clinical trial/research team at a site.

7.2 Abbreviations

For purposes of this procedure, unless otherwise stated, the following abbreviations shall apply:

Abbreviation	Expanded abbreviation
CMO	Chief Medical Officer
DP	Designated Person
EMR	Electronic Medical Record
GCP	Good Clinical Practice
HREC	Human Research Ethics Committee
LREP	Low Risk Ethics Panel
MACH	Melbourne Academic Centre for Health
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PI	Principal Investigator
QA	Quality Assurance
RGO	Research Governance Office

8. Procedure Detail

8.1 Procedure Statement

Western Health will:

- Maintain robust systems for the governance and management of research including:
    - Approval of research projects by a properly constituted research and ethics committee;
    - Approval of quality assurance activities by appropriate mechanisms;
    - Disclosure of conflicts of interest;
    - Reporting and investigation of adverse events and study breaches;
    - Monitoring and audit of appropriate records to ensure compliance with legislative requirements;
    - Systems to manage data and protect privacy and confidentiality;
    - Ensure adequate resourcing & financial management;
    - Use of Human Bio-specimens in Research;
    - Ensure Legal and insurance compliance;
    - Record Qualification & Credentials of all researchers;
    - Manage External Researchers & Study Monitors
    - Handling of Complaints;
    - Monitor the outcomes of research including completion of projects, publications, and communications.
    - Ensure compliance to relevant regulatory and legislative requirements
- Facilitate and promote appropriate research within Western Health.
- Support the advancement of knowledge and understanding of research through education and training.
- Provide guidance and expert advice for research grant applications.

8.2 Procedure Details

8.2.1 Ethics Approval and Governance Authorisation

All research and quality assurance projects undertaken at Western Health or involving Western Health staff, patients, or other resources must be submitted to the Office for Research for review and approval/authorisation prior to commencement. The research should comply with current regulations governing occupational health and safety, conditions of use of hazardous materials including ionizing substances, toxic chemicals, gene technology, and waste disposal. Researchers must submit all the requirements as listed on the Western Health website for ethics or governance applications.

The Office for Research will undertake a site-specific assessment / governance review of each project which includes ensuring that all projects involving human research have been reviewed and approved by an NHMRC certified Human Research Ethics Committee (HREC) or the Western Health Low Risk Ethics Panel (LREP). Research projects should not commence at Western Health until after written approval/authorisation of the site-specific research governance application has been issued by the Western Health Office for Research.

Western Health encourages staff to undertake research in collaboration with its campus and precinct research partners via the following research pathways:

- Clinical Audit, Quality Assurance Activity or Negligible Risk Research Projects:
    - The Office for Research will review and provide an organisational oversight approval (*i.e.*, a notification that the activity meets the criteria for exemption of ethics review) including governance review and authorisation.
- Negligible Risk Type Research:
    - Apply for ethics approval and governance authorisation from the Western Health LREP via an expedited pathway
- Low Risk Research:
    - Apply for ethics approval and governance authorisation from the Western Health LREP.
    - Or where the project is multi-site and has received ethics approval from a certified HREC apply for governance review and authorisation from Western Health Office for Research.
- High Risk Research:
    - Apply for ethics approval by an NHMRC certified HREC, apply for governance authorisation from Western Health Office for Research.
- Multisite research:
    - Apply for ethics approval by an NHMRC certified HREC, apply for governance authorisation from Western Health Office for Research.

8.2.2 Conflict of Interest

All conflict of interest matters that may arise by persons involved in the conduct, review, or administration of research must be clearly declared. If researchers are conflicted, this should be declared in their ethics submission with an explanation of how the conflict will be managed to ensure it does not compromise the research project. The reviewing LREP or HREC committee will determine if the declared conflict of interest needs to be further explored or they are satisfied that it will be adequately managed.

If any persons reviewing or administering research has a conflict of interest with a particular project, they must declare in writing that conflict of interest to either the Director of Clinical Research, Research Program Director or the LREP Chair. If any of these positions are conflicted, then the declaration should be made to the Chief Medical Officer (CMO) who will advise how the matter will be managed.

8.2.3 Safety Reporting

All Safety Reporting of Research must be in accordance with Western Health SOP 003 – Communication with HREC, Trial Sponsor and Insurer and Western Health SOP 009 – TGA Notification and Safety Reporting and NHMRC Monitoring and Safety reporting of Research Projects Guidelines.

The NHMRC publication Safety monitoring and reporting in clinical trials involving therapeutic goods (2016) sets out the requirements for the monitoring, collection and reporting of adverse events and adverse reactions that occur in clinical trials.

The NHMRC publication sets out definitions of:

- Serious adverse events (SAEs);
- Serious adverse reactions (SARs);
- Suspected unexpected serious adverse reactions (SUSARs);
- Unanticipated serious adverse device effects (USADEs);
- Significant safety issues (SSIs);
- Urgent safety measures (USMs).

The sponsor, through their independent safety monitoring arrangements, has the primary responsibility for monitoring the ongoing safety of the investigational medicinal product or device. The HREC/ Western Health Office for Research should be satisfied that the sponsor's arrangements are sufficiently independent and commensurate with the risk, size, and complexity of the trial.

It is the responsibility of Sponsors, Contract Research Organisations, Investigators, Institutions, and their delegates, of clinical trials involving therapeutic goods that were approved/authorised by the Western Health Office for Research to also comply with the reporting requirements in NHMRC document: *Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods November 2016*.

The Principal Investigator (PI) should ensure that the Western Health Office for Research is notified of all Significant Safety Issues (SSIs) occurring at the Western Health site that adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial. Western Health RGO should be notified without undue delay and no later than 72 hours of the Principal Investigator becoming aware of the event.

8.2.4 Research Breaches

Western Health is committed to ensuring that Research conducted at Western Health or on behalf of Western Health is performed to the highest possible standard. All Research breaches and misconduct will need to be reported and managed in accordance with the procedure outlined in the Western Health Research Code of Conduct (2023).

The Director of Clinical Research is Western Health's Designated Person (DP) for handling research misconduct allegations or if not available or otherwise conflicted, the Research Program Director can be approached. Allegations of research misconduct or breaches of the Australian Code or Western Health Research Code of Conduct at Western Health can be sent by email to research@wh.org.au. The DP receives a written allegation, conducts a preliminary investigation, and provides advice to the CMO or delegated officer. The DP must maintain full records of all matters that relate to allegations of research misconduct.

Breaches will require specific action by supervisors and responsible officers of Western Health.

Research misconduct may include (but is not limited to) fabrication, falsification, plagiarism, or deception in proposing, carrying out, or reporting the results of research, and failure to declare or manage a serious conflict of interest. It includes avoidable failure to follow research proposals as approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, animals, or the environment. It also includes the wilful concealment or facilitation of research misconduct by others.

Repeated or continuing breaches may also constitute research misconduct and will be considered as such where these have been the subject of previous counselling or specific direction.

Western Health regards any incident involving proven scientific misconduct as serious and will take appropriate action. Such actions may even include dismissal in accordance with Western Health Disciplinary Procedure and relevant laws.

Disciplinary action may also be taken against a complainant who is found to have made a malicious or vexatious allegation against a colleague.

8.2.5 Monitoring and Audits

Monitoring of research projects is an important means by which Western Health ensures that research conducted under its auspices is conducted in accordance with good clinical practice and approved ethical guidelines as well as Western Health

requirements. All research projects undertaken at Western Heath are subject to monitoring/auditing by the Office for Research where investigators must comply.

It includes verifying that the conduct of the research conforms to the approved proposal and any applicable requirements. This includes review of reports (annual, final, amendments, adverse events, non-serious breaches and serious breaches etc.) and audit of research projects.

Any amendments made to the project documents; protocol, participant information and consent form, questionnaires/surveys and/or changes or additions of new research personnel, researchers must seek approval from the Reviewing HREC/Western Health LREP and obtain authorisation of these amendments from the Western Health Office for Research before implementation.

Monitoring and Auditing conditions:

- The Office for Research instigated Audits include Self-Audits, Desktop and Onsite Audits. All projects (Site Governance, Quality Assurance (QA) and Low Risk) undertaken at Western Health may be subjected to audits. The Office for Research may conduct a planned or random audit on any aspect of the research project. The audit may be conducted by an internal or external individual with the appropriate expertise related to the research project. The Principal Investigator will be notified prior to the audit with relevant details and timeframes.

- As a condition of ethics approval & governance authorisation, an annual progress report is required on the anniversary of ethics and governance approval date, or as requested by the reviewing LREP/Western Health Office for Research. Each Annual Progress Report or Final Report must include a Self-Audit Report which must be submitted to the Office for Research by the Principal Investigators (or their delegate).

- Continuation of ethics approval is contingent on submission of an annual report, due within one month of the ethics approval anniversary/annual report due date. Failure to comply with this requirement may result in suspension of the project by the LREP/Western Health Office for Research. If the study has completed, a final report should also be sent to the Office for Research upon completion of the project.

- Fines, Suspension and /or Withdrawal of a research project may occur if:
    - Investigators fail to supply completed Annual Reports or a Final Report.
    - The conduct of a research project is found to be non-compliant with the HREC's/ Western Health LREP or Western Health Office for Research's conditions of approval.
    - There are concerns about the welfare or safety of participants.
    - There are concerns regarding the safety of the project.

- Researchers should contribute to research monitoring through processes, which include:
    - Self-audit;
    - Implementation of a study monitoring plan;
    - Provision of regular reports as required by the institution;
    - Provision of regular reports as required by the reviewing ethics committee;
    - Provision of regular reports as required by funding bodies;
    - Prompt notification on adverse or unwanted events.

Findings arising from monitoring should be used to develop corrective and preventative actions where required, to ensure compliance, the rights and well-being of participants are protected, and the study data are credible.

8.2.6 Data Management in Research

The responsible conduct of research requires researchers to act in a manner that demonstrates honesty and integrity. This includes proper management and retention of the research data. Further guidance and details found in *OG-GC7 Data Management in Research.*

The access, collection, analysis, dissemination, retention, and destruction of research data needs to abide by the Western Health Research Code of Conduct policy (2023). When in doubt, guidance should be sought from the Office for Research or from the Western Health Corporate Records Manager.

Western Health asserts ownership of all research materials and data generated by researchers in the course of their duties at Western Health, notwithstanding separate arrangements made as part of a contract of employment, Research Collaboration Agreement(s) or other Intellectual Property Agreements. Where research undertaken by staff involves an invention or creation, staff should familiarise themselves with the *P-GC7 Intellectual Property and Moral Rights*. This policy clearly defines how intellectual property ownership and distribution will be managed.

Research data and metadata should be collected, stored, retained, used, shared, and disposed of in a manner that protect the privacy, rights, safety, and well-being of the research participants and the wider community, maintains data integrity and is in accordance with all applicable requirements (including Western Health, legislative, guidelines, legal, ethical, and funding bodies', study agreements etc.) at each stage of the data lifecycle.

Original data and metadata should not be removed from Western Health and should be accessible at all times.

Researchers should not remove copies of any data from Western Health without approval from the Principal Investigator, Head of Department (HoD), Director of Clinical Research and Research Program Director (except where the movement of data described in the ethically approved study protocol and agreements). Appropriate agreements should be in place prior to movement of data. This requirement includes when researchers leave the organisation.

Research staff should plan data management requirements and processes for each study as part of the study planning activities i.e., with the start of protocol development or on approach to participate in a research study by an external party (*i.e.*, collaborator or commercial sponsor).

A data management and data access plans should be developed and included in the project protocol, other research documentation and ethics and governance submission.

Researchers must ensure the integrity of their research. Research data must be accurate, complete, authentic, and reliable. Research data should be recorded in a form that is adequate for verification of research results. As data may need to be reviewed for the verification of results and reference some time into the future, data must be stored in a durable and secure format. Researchers who use electronic storage should only use Western Health shared drive/SharePoint or REDCap to ensure backup of storage through the Western Health ICT systems. No external hard drives, USBs, or personal storage solutions (*e.g.*, Dropbox, Google Drive) can be used.

Western Health and researchers have a responsibility to ensure that information is used appropriately. This means that consent has been obtained where it is inappropriate to use the information without consent; that data are secured to ensure privacy and that data are stored for the required length of time and subsequently destroyed in an appropriate manner.

8.2.7 Medical Records

Ensure that the evidence of participation (content, visits, tests and clinical notes) are included in the participant/s medical record, relevant information should be communicated to other clinical teams where the trial intervention has clinical implications.

All project/trial procedures that are involved/part of patient clinical care are recorded in an appropriate section of their medical record (clinical note/clinical trial notes).

8.2.8 Resource, Facilities and Finance

Budgets for Research:

- If the project is funded, a detailed budget (signed and dated by the PI) should submitted to the Office for Research as part of the Ethics/ Governance Submission.

- Researchers should ensure that Research Budgets are discussed with their appropriate Divisional Business Analyst (BA) or Operational Manager as required prior to submission. Please note that contracts or expenditure requests exceeding $250K require a Business Case or CEO signature (see link here for further information).

- Endorsement of the project budget is required as part of the Contracts/Agreement endorsement process. This endorsement can be provided via sending a copy of the BA email confirmation to researchagreements@wh.org.au or as per arrangements with respective BAs that are currently in practice across various departments.

- Study investigators or contact will upload all relevant Research agreements and associated documentation as required onto e-PACE for organisational endorsement and approval.

Resourcing and Facilities:

- Ensure available resources before conducting research e.g., research personnel & expertise, funding, equipment, storage, approval from departments involved in the project etc.

- A Statement of Approval is required and must be provided for each Western Health department whose services will be required to undertake your research. The following service departments have separate review requirements as outlined on the Western Health Office for Research website:

    - Pathology;
    - Medical Imaging;
    - Medical Physicist Assessment;
    - Health Information Services;
    - Performance Unit;
    - Pharmacy;
    - Language Services.

- Appropriate agreements are also required when engaging external partners.

8.2.9 Use of Human Biospecimens

Ensuring all research projects involving the use of human biospecimens have been reviewed and approved by an NHMRC certified HREC before approval of the site-specific research governance can be finalised.

Use of human biospecimens in research must be in accordance with the National Statement on Ethical Conduct in Human Research (2018 and updates) and any relevant legislative requirements. In particular, research involving human biospecimens must observe the fundamental ethical principle of respect for the donor, including the provision of full information and donor consent (where feasible), professional removal of samples, and secure storage of these to maintain confidentiality and privacy. The cultural or religious sensitivities of the donor should be considered when soliciting or accepting human biospecimens. The use of human biospecimens in research at Western Health must be carried out in accordance with the reviewing Ethics Committee requirements.

8.2 10 Research Agreements, Insurance and Indemnity

All research must have in place an agreement that clearly sets out the obligations and responsibilities of each party. Furthermore, the agreement should define the insurance requirements that need to be in place to cover the respective liabilities of the parties. There are a number of pre-approved Western Health agreements (Standard agreements) that can be used without any change, other than entry of project specific details, and do not require to be legally reviewed again. All insurance and indemnity clauses in any Agreement that have been changed from what is contained within the Western Health pre-approved suite of Standard agreements must be reviewed by Western Health Office for Research and Western Health Legal if required prior to being accepted.

All collaborative research in which Western Health is involved requires execution of an appropriate research collaboration agreement before research can commence. The agreements/contracts for all research projects undertaken by staff of Western Health or involving Western Health resources must be reviewed and endorsed by Western Health Office for Research or if required Western Health Legal Counsel. Such written endorsement must be included with new research project applications as part of the site-specific research governance application to the Office for Research.

- Standard Agreements are reviewed and endorsed by the Office for Research (these agreements are pre-approved that can be used without any changes, other than entry of project specific details, and do not require to be legally reviewed again). Standard Agreement Templates include:

    - Medicines Australia Agreements;
    - Western Health Research Collaboration Agreements (RCA);
    - Western Health Memorandum of Understanding (MOU);

- Melbourne Academic Centre for Health (MACH) Agreement.

- Non-Standard Agreements are required to be reviewed and endorsed by Western Health Office for Research and /or if required Western Health Legal Counsel.

For commercially sponsored clinical trials, a copy of the sponsor's certificate of insurance is submitted. This should comply with the Victorian Managed Insurance Authority (VMIA) minimum requirements for clinical trials insurances:

- Detail the type of insurance – Public and Product Liability - or equivalent such as General Liability or Clinical Trials Insurance.
- Include as a named insured the full, legal name of the Australian entity acting as a Sponsor.
- Detail the period of insurance.
- Provide insurance coverage for a minimum of $10million AUD for any one occurrence and in the annual aggregate
- Not contain an excess/deductible, or self-insured retention amount greater than $25,000 AUD for each and every claim or series of claims arising out of one original case.

For commercially sponsored trials, the Medicines Australia Standard Form of Indemnity must be provided. WH researcher must not provide a separate indemnity to any other party without prior approval of such by Western Health Legal and notification to the Office for Research evidencing this approval.

8.2.11 Research Qualification and Credentials

All members of the research/ clinical trial workforce require evidence of documented training in safety and quality responsibilities for clinical trial service delivery, Good Clinical Practice (GCP), and roles and functions in the operation of the Australian Commission on Safety and Quality in Health Care National Clinical Trials Governance Framework.

All staff undertaking research must have expertise and relevant qualifications in a discipline relevant to the project. Western Health Investigator Curriculum Vitae (CV) is to be provided and submitted to the Office for Research every two years; researcher to sign the most current declaration that they have read and understood the Western Health Research Code of Conduct (2023). If researchers do not use the Western Health Investigator CV template, they are required to provide a signed and dated full CV with a signed and dated Western Health Research Code of Conduct (2023) declaration.

It is mandatory for all personnel involved in research to have a valid GCP certificate. A certificate of completion is provided to the Office for Research. Western Health has recognised the certification process that TransCelerate Biopharma Inc. has implemented to recognise GCP training courses that contain material meeting the minimum criteria agreed to by its member organisations: http://www.transceleratebiopharmainc.com/wpcontent/uploads/2013/10/TransCelerate-GCP-Training-Minimum-Criteria-in-Operating-Principles_0.pdf); see also: http://www.transceleratebiopharmainc.com/gcp-trainingattestation/#headline4.

All personnel involved in clinical trials are required to complete a mandatory Australian Clinical Trials Education Centre (A-CTEC) online module “Introduction to Clinical Trials” and upload the completion certificate to WeLearn platform to obtain endorsement from the Office for Research.

8.2.12 External Researchers and Monitors

Where projects collaborate with an external institution or external researcher, and they wish to conduct research at Western Heath, an Honorary Researcher appointment for the external personnel must be organised in order for the external researcher to gain access to Western Health data, facilities, or contact patients or staff. Refer to *OP-EP1 Honorary Appointments* for more details.

For Commercially Sponsored Clinical Trials only – External study monitors are required to complete and sign the Approval to Examine Medical Records Form. Electronic Medical Records (EMR) training is required prior to their access to medical records.

8.2.13 Collection of Research Participant Feedback

In adherence to the NSHQS Standard 8 – *Partnering with Consumers*, WH strongly encourages clinical trial research participants to provide feedback on their experiences and share their thoughts on how Western Health as an organisation can continue to improve clinical research implementation. An anonymous online Clinical Trial Participant Experience Survey on the Western Health REDCap System is available and advertised to trial participants.

It is the responsibility of our Clinical Trial Services to ensure that all Clinical Trial Participants are aware they have the opportunity to provide their feedback and access to the Clinical Trials Participant Feedback Survey. The survey is managed by the Office for Research and the feedback data will be exported and analysed on a regular basis and aggregate results will be disseminated to respective departments and relevant stakeholders.

8.2.14 Handling Complaints

Complaints may be made about researchers, the conduct of research, or about the conduct of a LREP or other review body. Complaints may be made by research participants, researchers, staff, or others. All complaints should be handled promptly and sensitively. Complaints can be received in verbal or written formats:

- Complaint management must be sensitive towards the rights, need and concerns of reporters, complainants, patients, research participants, and researchers.
- Complaint management must comply with the Victorian Information Privacy Act 2000, the Health Records Act 2001, and the Health Services (Conciliation and Review) Act 1987.
- All reporters, complainants, patients, research participants, and investigators have a right to report or complain either in person or through a representative.
- All complaints will be treated confidentially.
- It is the responsibility both of the Office for Research and the LREP to ensure that the process is easily accessible to all concerned.
- The Office for Research will record details of complaints in the research complaints registry.

The evaluation of complaints helps to inform the Office for Research and the LREP about areas where processes can be improved, particularly in relation to research management.

The Research Program Director or the Office for Research Manager are the designated persons to receive complaints from research participants/researchers/LREP Members and Other Interested Persons. It is expected that most complaints from research participants/researchers/LREP Members and Other Interested Persons will be able to be dealt with by the Research Program Director in conjunction with the relevant PI.

Consumers, including research participants can provide Feedback via the Western Health Feedback Process on the Western Health website. If a Research Complaint is received via this mechanism, then it will be referred to the Office for Research for review by the Research Program Director or Office for Research Manager and logged on the Research Complaints Register.

The decision as to whether an incident/complaint is minor or serious will be made by Research Program Director and/or the Office for Research Manager in consultation with the Chair of the LREP and, where necessary, the Director of Clinical Research.

Research related complaints will be reported to the approving Ethics Committee and/or the Western Health Board as part of the annual Western Health Board report.

All Research complaints received by the Research Program Director (RPD), Manager, Office for Research will be entered onto the REDCap Research Complaints Register. They will be reviewed by the RPD and a resolution sought. All complaints data will be reported to the relevant committees on a bi-annual basis.

- Serious complaints, which cannot be readily resolved, will be referred for further consideration by the Research Program Director, LREP Chair and Director of Clinical Research to the Chief Medical Officer.
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- In circumstances where a complaint cannot be resolved using Western Health's internal complaint resolution processes, external, independent advice will be sought. This may include consultation with the Office of the Health Services Commissioner, or with senior staff from partner institutions.
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- Complaints which highlight problems warranting amendments to the research protocol will be reviewed by the approving Ethics Committee who will provide written advice to the PI.

8.2.15 Research Publications

Dissemination of research results is typically through academic journals and books. The Australian Code refers to all forms of dissemination including non-refereed publications such as webpages, and other media such as exhibitions, film, as well as professional and international repositories.

All matters pertaining to how research can be published and authored will be dealt with in accordance with the guidance provided in the WH Research Code of Conduct. (2023).

WH has a responsibility to ensure that findings and advances in knowledge from publicly funded research are disseminated to other researchers and the wider community, subject to relevant restrictions on the publication of results where intellectual property needs to be protected, as outlined in the *P-GC7 Intellectual Property and Moral Rights*.

The following principles apply to publication of research findings

1. Researchers must ensure that their research findings are accurate and are reported in a complete, correct, and unambiguous manner.
2. Negative results should be reported where possible.
3. Potential conflicts of interest must be disclosed in accordance with the Western Health OP-RS2 Conflict of Interest Procedure
4. The same set or subset of data may not be published more than once, except where due reference is made.
5. Cite the work of other authors fully and accurately.
6. Clinical trials should be registered with a recognised register in order to promote access to information about clinical trials.

8.2.16 Compliance

All research at Western Health must comply with all relevant legislation, regulations, codes and guidelines as applicable and other regulations from time to time as listed in Section 5. All research at Western Health must comply with:

- National Statement on Ethical Conduct in Human Research (2007 updated2018).
- Australian Code for the Responsible Conduct of Research (2018).
- Australian Commission on Safety and Quality in Health Care National Clinical Trials Governance Framework.
- Other Research Guidelines as listed in Section 7 of this document.
- National Clinical Trials Governance Framework

8.2.17 Research Facilitation, Education and training

The Office for Research will facilitate the promotion of Research Education and provide training through the following avenues:

1. Email e-Newsletters;
2. Direct email notification to researchers;
3. Research Report;
4. Research and Best Care Conference;
5. Western Health Internal Research Grants;
6. Research Workshop
7. Research Modules on WeLearn

8. Research Club;

9. Academic Affiliations;

10. Western Health Organisational announcements;

11. Good Clinical Practice & Clinical Trial Principles Training Modules; Australian Clinical Trials Education Centre Training Modules

8.2.18 Research Grants

The Office for Research will support Western Health personnel with their Research Grant applications by providing submission guidance and expert advice. The Office for Research will maintain confidentiality regarding grant funding and project details.

The Office for Research will ensure that all National Health and Medical Council (NHMRC) grant funding supporting health and medical research conducted by Western Health, and any accrued interest, remains available to support research activities in accordance with NHMRC Deeds of Agreement.

8.3 Deviations and breaches to procedure:

- Any deviations from this policy will need to be reported to the Office for Research in a timely manner and not longer than 48hrs from when the deviation was discovered, with an explanation of why a deviation has occurred. For any pre-planned deviations/exemptions, a request should be made to the Office for Research requesting an exemption from any element(s) covered under this policy. The Office for Research will consider the request and provide their instructions within a timely manner. Outcomes of such a request will be final and cannot be contested.

- Any breaches of this policy must be reported to the Office for Research as soon as they are discovered. Subject to the severity of any breaches to be determined by the Office for Research, they may be subject to the processes governing Research Breaches and Misconduct as described *in the Western Health Research Code of Conduct (2023).*

9. Document History

Number of previous revisions: Nil

Previous version dates: Nil

Minor amendment: September 2023

10. References

Any reference to other policies, statutes, legislation or other sources that relate to this procedure should be listed in full detail here. Cross reference with External Accreditation Standards.

The external frameworks, standards & programs informing this procedure include:

10.1 Legislation

- Australian Research Council Act 2001 (Cth)
- Epidemiology Studies (Confidentiality) Act 1981 (Cth)
- Freedom of Information Act 1982 (Vic)
- Gene Technology Act 2001 (Cth)
- Gene Technology Act 2001 (Vic)
- Guardianship and Administration Act 1986 (Vic)
- Public Health and Wellbeing Act 2008 (Vic)
- Health Records Act 2001 (Vic)
- Health Complaints Act 2006 (Vic)
- Human Tissue Act 1982 (Vic)
- Infertility Treatment Act 1995 (Vic)
- Privacy and Data Protection Act 2014 (Vic)
- Mental Health Act 2014 (Vic)
- Narcotic Drugs Act 1967 (Cth)

- National Health and Medical Research Council Act 1992 (Cth)
- Prevention of Cruelty to Animals Act 1986 (Vic)
- Privacy Act 1988 (Cth)
- Payment of participants in research: information for researchers, HRECs and other ethics review bodies 2019 (NHMRC) (Cth)
- Prohibition of Human Cloning Act 2002 (Cth)
- Public Records Act 1973 (Vic)
- Biosecurity Act 2015 (Cth)
- Radiation Act 2005 (Vic)
- Therapeutic Goods Act 1989 (Cth)
- Charter of Human Rights and Responsibilities Act 2006 (Vic)

10.2 Guidelines, Codes and Regulations

- Australian Charter of Healthcare Rights 2008 (Cth)
- ICH Guidelines
- ICH Efficacy Guideline for Good Clinical Practice E6 2016
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - annotated with TGA comments
- Therapeutic Goods Regulations 1990
- Therapeutic Goods (Medical Devices) Regulations 2002
- The Australian Clinical Trial Handbook March 2006
- Access to Unapproved Therapeutic Goods- Clinical Trials in Australia October 2004
- Human Research Ethics Committees and the Therapeutic Goods Legislation June 2001
- Review of Quality Assurance Projects at Western Health
- Health Records Act 2001 (Vic) - Statutory Guidelines on Research issued for the purposes of Health Privacy Principles 1.1 (e) (iii) & 2.2 (g) (iii) - Office of the Health Services Commissioner (Victoria) February 2002 (Vic)
- Guidelines under Section 95 of the Privacy Act 1988 (Cth)
- Guidelines approved under Section 95A of the Privacy Act 1988 (Cth)
- Radiation Regulations 2007 (Vic)
- Code of Practice - Exposure of Humans to Ionising Radiation for Research Purposes 2005 (Cth)
- Statement on Consumer and Community Participation in Health and Medical Research 2016 (NHMRC)
- Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 8th edition, 2013 (NHMRC)
- Gene Technology Regulations 2001 (Cth) –Office of the Gene Technology Regulator and Associated Legislation and Regulations
- DNA Genetic Testing in the Australian Context: A Statement (NHMRC)
- Medical Genetic Testing - Information for Health Professionals (NHMRC) 2010
- Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical practice and research (NHMRC) 2017
- VMIA Clinical Trials Insurance and Risk Management Guidelines 2012 (Vic)
- National Statement on Ethical Conduct in Human Research (2018 and updates)
- Australian Code for the Responsible Conduct of Research (2018)Western Health Research Code of Conduct (2023)

11. Sponsor

Research Program Director

12. Authorisation Authority

Chief Medical Officer