Western Health

Western Health
Research Code of Conduct

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1 General Principles and Practices

1.1 Introduction

Western Health (WH) is a leading acute tertiary health service engaged in training and education of clinical and allied staff, and in the conduct of research across various disciplines.

Western Health has strong affiliations with a number of academic partners, predominantly the University of Melbourne, Victorian University and Deakin University. The former two academic institutions are exclusive partners of Western Health in the Western Centre for Health Research and Education building (WCHRE). The University of Melbourne also has the Western Clinical School which is located on site within the WCHRE.

Western Health (WH) and its staff are actively engaged in research in their own capacity, or, in partnership and collaboration with other onsite and offsite entities and researchers. WH's onsite academic partners also conduct their own research within the WCHRE or utilise WH facilities and/or access to patients and their data.

This WH Research Code of Conduct (the WH Research Code) outlines the general standards of professional and ethical conduct of staff whilst engaged in research on behalf of WH, or conducting research on WH premises and/or patients and their data. For research conducted by any of the WH academic partners where there is no apparent or foreseeable involvement or impact for Western Health, the Code of Conduct of the academic partner will take precedence over the WH Research Code, except where there are explicit obligations owed to WH in the conduct of such research.

Researchers must ensure that their project has received all applicable ethics and governance approvals prior to the project commencing. Retrospective ethical approval is not possible, and pending on the nature of the research project, failure to obtain appropriate approvals may constitute a breach of the WH Research Code and/or other institutional, legislative and statutory requirements.

Non WH researchers accessing Western Health data must ensure that they have an honorary appointment with WH that allows them to conduct aspects of their research at WH. For all CTN notifiable research, or research involving an intervention on a Western Health patient, the Principal investigator must be an employee of Western Health. Non WH staff of a research team that may be implementing an intervention on a Western Health patient will need to get clearance from the respective WH department in which the intervention would otherwise be provided. These staff must be suitably credentialed and provided with an honorary appointment which meets the requirements of provision 7.8 of the WH Honorary Appointment policy.

In the context described in this document, the term 'research' refers to the original investigation of ideas in order to gain knowledge and make this widely available.

1.2 Central Reference Documents

The following documents are central to the operationalization of the WH Research Code of Conduct. These documents will help guide how the WH Research Code of Conduct will be interpreted and inform how certain aspects of this WH Research Code of Conduct are to be enacted.

Namely, the following documents are central to the interpretation and execution of the WH Research Code of Conduct

1. Australian Code for the Responsible Conduct of Research 2018
2. National Statement on Ethical Conduct in Human Research (2007) – Updated 2018
3. WH Code of Conduct P-EP2
4. Honorary Appointments OP-EP1
5. Professional Misconduct and Reportable Conduct Scheme OP-EP2
6. Disciplinary Procedure: OP-EP2
7. Intellectual Property and Moral Rights: P-GC-7
8. Research, Ethics and Governance Policy P-GC7

All other related references, guidelines and Acts that need to be considered as part of the WH Research Code of Conduct are listed at the end of this document. Awareness of, and adherence to the relevant references, guidelines and Acts will ensure that all research is conducted in accordance with legislative and statutory requirements.

This document may not contain the complete list of all the guidelines that you may need to familiarise yourself with. As such all researchers should familiarise themselves with any additional guidelines and regulatory requirements that are unique to their particular research area or a requirement of their designated employer.

1.3 WH Research Code Guiding Principles

While carrying out their roles, staff involved in the conduct of research are responsible for –

i. Ensuring that their research has all the necessary ethical and governance approvals prior to commencing
ii. Demonstrating intellectual honesty and integrity in proposing, performing and reporting research accurately;
iii. Maintain adequate documentation to support decisions made;
iv. Responsible communication of research results;
v. Transparency in declaring and managing actual or potential conflicts of interest;
vi. Appropriate acknowledgement of the role of others, and the application of appropriate criteria for determining authorship;
vii. Good stewardship in sharing resources for research including information;
viii. Fairness in peer review;
ix. Respect for human research participants, animals, safety and the environment;
x. Reporting research misconduct when becoming aware of any unethical behaviour or wrongdoing by any employee[1]
xi. Ensuring that appropriate supervision is afforded to trainee researchers;

All employees conducting research or responsible for it are required to familiarise themselves with the WH Research Code and are personally accountable for acting in accordance with its principles. All employees are responsible for upholding professional and ethical standards, for continually enhancing WH's and/ or their partners reputation through the quality of their work and conduct, and for contributing to sustainable performance and delivering value to stakeholders and the broader Western Community.

1.4 Scope

This WH Research Code of Conduct (WH Research Code) applies to all WH employees, and other related staff, for their conduct while carrying out their WH research duties, conducting research on WH premises, patients and/or using WH data, or whilst acting on behalf of WH.

This WH Research Code also applies to WH's academic partner employees, students and honorary affiliates while on WH premises (and/or requesting access to WH facilities remotely) under the Terms of any formal Agreement that is in place or any other arrangements as appropriate. For staff with appointments across both WH and any of its academic partners, the manner by which the WH Research Code will be enacted will be through discussions and agreement with the relevant academic partner(s), as deemed appropriate by the matter under consideration.

All WH staff and students engaged in the conduct of research should familiarise themselves with the WH Research Code and also the relevant research Code or guidelines of the institution that they may also hold a partial or honorary appointment with or have a related association or affiliation that may entail them to conduct research on their behalf.

[1] Responsibilities of researchers adapted from the Australian Code for the Responsible Conduct of Research. Part A – Principles and practices to encourage responsible research conduct. Australian Code

1.4.1 WH Research Code Specific Requirements

The WH Research Code is underpinned on the "Australian Code for the Responsible Conduct of Research. Part A – Principles and practices to encourage responsible research conduct" which helps guide the responsible conduct of research in Australia. The WH Research Code also takes into consideration WH's own institutional code of conduct requirements and also those of its close affiliated partners and funding bodies such as the University of Melbourne, Victoria University, Deakin University and the NHMRC as deemed appropriate.

The WH Research Code identifies the following specific requirements for staff engaged in the conduct of research at WH:

- Primary Materials and Research Data
- Publication and Authorship
- Supervision of Students Undertaking Research
- Collaborative Research
- Conflict Of Interest
- Breaches of the WH Research Code, Research Misconduct and Allegations
- Intellectual Property
- Requisite Approval and Licenses for Research

It is a requirement that WH staff engaged in the conduct of research familiarise themselves with the WH Research Code and ensure that its provisions are adhered to.

More detailed policies and guidelines pertaining to the abovementioned specific requirements are contained within this, the WH Research Code for Research document.

1.5 Advice

Where a researcher or any staff member of WH is in doubt as to the applicability of the provisions of the WH Research Code, or the course of action that should be taken in relation to it, advice should be sought from the Research Program Director (RPD), Director of Clinical Research (DCR), or Office for Research. Such advice should be provided in confidence.

If there is doubt about any aspect of an employee's conduct, the detailed WH policies and procedures can be consulted or the matter can be referred to the RPD for advice in the first instance, if the Head of Unit or Department is not the appropriate or preferred option.

Breaches of the Code must be reported and will be investigated. Subject to any findings, this may entail disciplinary action.

1.6 WH Research Governance

All WH research needs to be conducted in accordance with the WH Research Authorisation and Governance procedures that have been established to afford WH research governance oversight and where applicable International Conference on Harmonisation Good Clinical Practice (ICH-GCP) compliance. These documents and procedures are available on WH inter and intranet and all required documents are available for downloading. The WH Research Governance Officer is available to provide further guidance and assistance with these and other governance matters.

Researchers must ensure that their research has received the necessary ethics approval and research governance authorisation prior to commencing their project. Failure to do so will be in breach of the WH Research Code and other institutional, legislative and statutory requirements.

1.7 The Australian Code

The Australian Code for the Responsible Conduct of Research (the Australian Code) (2018) guides institutions and researchers in responsible research practices and promotes integrity in research for researchers.

The Australian Code guides research staff how to:

- manage breaches of the Code and allegations of research misconduct
- manage research data and materials
- publish and disseminate research findings, including proper attribution of authorship
- conduct effective peer review; and
- manage conflicts of interest

The Australian Code also explains the responsibilities and rights of researchers if they witness research misconduct.

Developed jointly by the National Health and Medical Research Council, the Australian Research Council and Universities Australia, the Australian Code has broad relevance across all research disciplines. It replaces the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice (1997)*.

Compliance with the Australian Code is a prerequisite for receipt of National Health and Medical Research Council funding. Regardless of the source of research funding, Western Health expects all its staff and students to comply with the requirements of both the WH and the Australian Codes.

1.8 Definitions

ARC	Australian Research Council (grant funding body)
Australian Code for the Responsible Conduct of Research (2018)	Guide for responsible research conduct in Australia, published by NHMRC and ARC in 2018 and available at: Australian Code A reference for the development of appropriate institutional policies and procedures ("the Code").
National Statement	The *National Statement* on Ethical Conduct in Human Research, 2007 updated 2018(*National Statement*) consists of a series of Guidelines made in accordance with the National Health and Medical Research Council Act 1992 (the Act) National Statement
Western Health (WH)	The institution that has created and is responsible for this Code
WH Code of Conduct	Code of Conduct for Researchers at a WH Campus or with remote access to WH data systems. Refer Policy guide P-EP2
WH Honorary Appointments	Process by which honorary appointment will be made and processed Refer Addendum No/2
WH Reporting of Professional Misconduct	Process by which professional misconduct will be reported and managed at Western Health Refer Policy Guide OP-EP2
WH Disciplinary procedure	Procedure defining how disciplinary action will be managed once misconduct is confirmed Refer Procedure Guide OP-EP2
WH Intellectual Property and Moral Rights	How the invention or creation of intellectual property will be managed for research conducted by WH staff Refer Policy Guide P-GC7

2 MANAGEMENT OF PRIMARY MATERIALS AND RESEARCH DATA

2.1 Introduction

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. The purpose of this Policy is to assist researchers to fulfil their responsibilities with respect to the storage and retention of data and records associated with, and arising from, their research activities. The policy requires that durable records are retained from research practices in order to justify the outcomes of the research and to defend them if they are challenged.

WH asserts ownership of all research materials and data generated by researchers in the course of their duties at WH, 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 WH Intellectual Property and Moral Rights policy. This policy clearly defines how intellectual property ownership and distribution will be managed. Please refer to Addendum 5.

2.2 Scope

This policy applies to all WH employees, and other related staff, for the management of primary materials and research data that is generated as a result of carrying out their WH research duties or whilst acting on behalf of WH.

Employees, students and honorary affiliates of WH's academic partners will need to adhere to their institutional policy on how primary materials and research data are to be managed for research conducted on behalf of their institution, with due consideration to any background or other intellectual property and resources that WH may have contributed as part of a collaborative project. Such matters should be dealt by a collaborative agreement or equivalent document. Please visit the WH Office for Research web site for more information: Office for Research Webpage or Medicines Australia Clinical Trial Agreements

2.3 Procedure

2.3.1 General

i. Data and records must be clear, accurate, complete and in sufficient detail to enable validation of research results.
ii. Data, including electronic data, should be retained in a durable, indexed and retrievable form.
iii. Where permissible, research data should be made available for use by other researchers or as addenda to publications unless this is prevented by legislative, ethical, privacy or confidentiality considerations.
iv. Researchers given access to confidential information must maintain that confidentiality. Confidential information can only be used in ways agreed with those who provided it or as required by law. Particular care must be taken when discussing this data.[2]
v. Non-clinical research data must be retained for a minimum of 5 years post the date of any related publication, or longer if the data possess further result discussion potential, if there are regulatory or sponsor requirements or if the data has historical or archival value.
vi. Clinical data must be retained for 7 years after the last occasion on which a health service was provided to the individual by the provider.
vii. Researchers must be aware of confidentiality restrictions, any relevant agreements that affect access to or disclosure of and report any breach of confidentiality to the head of the department.

[2] Responsibilities of researchers adapted from the Australian Code for the Responsible Conduct of Research. Part A – Principles and practices to encourage responsible research conduct.
https://www.nhmrc.gov.au/file/14384/download?token=gje4DNtT

2.3.2 Electronic Documents and Data

i. Researchers should give due consideration to how the quality, safety and integrity of their research data and records can be achieved. It may be important to have audit trails or other physical, logical, or procedural security measures in place to ensure the integrity and trustworthiness of the records and data generated.
ii. Researchers will store electronic documents and data on a designated network drive on WH servers or on other appropriate platforms that will ensure the protection of the data and its integrity.
iii. Research data and related documents should be backed up at regular intervals so that documents and data can be retrieved from the backed-up copies should the need arise. Research documents or data must not be stored on local drives / desktops or removable storage devices other than on an immediate basis (e.g. for working off line on a file or document after hours or while out of the office). The latest version of the amended file or document must be saved to the relevant network drive at the earliest opportunity.
iv. Creating, managing and using information from research databases is the responsibility of the research units and needs to be resourced through funds held by research units.
v. The establishment of a databank should be in accordance with the relevant WH Data Management in Research (Guideline OG-GC7)
vi. To help address a number of research related data capture and storage regulatory requirements, it's a requirement for WH initiated projects to be conducted using REDCAp as the data capture platform. It is a condition of research governance approval at WH that research projects are conducted using REDCAp. Permission to use other platforms must be approved by the Office for Research to ensure governance authorisation is granted.

2.4 Clinical Trials

The conduct of clinical trials is regulated by the Therapeutic Goods Administration (TGA). Researchers conducting clinical trials are required to comply with the "Note for Guidance on Good Clinical Practice" (CPMP/ICH/135/95) available at ICH Guideline for Good Clinical Practice. Specifically, in regards to documentation, data management and handling, the following requirements are extracted from Section 5.5:

When using electronic trial data handling and/or remote electronic data systems, the sponsor should:

i. Ensure and document that the data processing system(s) conforms to the sponsor's established requirements for completeness, accuracy, reliability and consistent intended performance (i.e. validation).
ii. Maintains SOPs for using these systems.
iii. Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e. maintain audit trail, data trail, edit trail).
iv. Maintain a security system that prevents unauthorised access to the data.
v. Maintain a list of individuals who are authorised to make data changes.
vi. Maintain adequate backup of the data.
vii. Safeguard the blinding, if any (e.g. maintain the blinding during data entry and processing).

All WH researchers are encouraged to discuss their proposed research endeavours with the WH Office for Research in order to gain assistance in this regard.

Researchers engaged in the conduct of clinical research involving humans should ensure that they have successfully completed an accredited Good Clinical Practice (GCP) course in the last 3 years before assuming the role of a Principal Investigator on a clinical trial.

Principal investigators (PI) on a clinical trial at WH must have practicing rights at WH and be in a position to be able to adequately fulfil their PI responsibilities in the conduct and management of the trial, trial staff and trial participants in accordance with GCP requirements.

2.5 Retention of Records

Researchers will at all times comply with the legal requirements for retention of records. Minimum retention durations are as follows:

Research Output	Minimum retention period for original research data
Journal publication	Five (5) years from the date of latest publication
Graduate Thesis	12 months (1) years from the date of publication
Clinical trial	Fifteen (15) years from the termination of the study or as otherwise defined by the Statute of Limitations or requested by Sponsor, whichever is the longest.
Clinical Trial with Children	Data must be kept for at least 25 years after the completion of a clinical trial
Patent	Twenty (20) years
Gene therapy (patient records)	Permanent

2.6 Destruction

Researchers must give due consideration when destroying data, that the destruction of the data will not compromise or violate any legislative or statutory requirements or minimise the potential for future research. The destruction of research data and records should be authorised by the Head of Department or RPD on recommendation of the researcher. Due care must be taken to ensure privacy when destroying research records. Refer to the: Victorian Health Records Act 2001

2.7 Laboratory Notebooks

Western Health does not directly undertake basic research that necessitates the establishment of laboratory notebooks by its own researchers. However, a number of its onsite academic partners occupy laboratory space within the WCHRE and conduct research that would necessitate the creation and maintenance of a laboratory notebook. Researchers involved in laboratory-based research should adhere to their institution's policy and procedures that govern the creation, maintenance and archiving of laboratory notebooks. In the instance where a WH researcher's project does necessitate the creation of a laboratory notebook, the researcher should seek the guidance of the universities in relation to the creation, maintenance and archiving of the laboratory notebook, or any of the other academic partners with whom they may have an affiliation.

3 Publication and Authorship

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. [3] It is the intention of this WH Research Code to cover the publication and authorship breadth as defined by the Australian Code.

3.1 Aim

i. To ensure WH's compliance with the Australian Code for the Responsible Conduct of Research with regard to publication, dissemination of research findings and authorship.
ii. To provide guidelines on criteria that determine what level of contribution should be recognised through authorship on a scientific paper.
iii. To establish lines of responsibility of authors and procedures to follow pre-submission and post journal acceptance of a publication.

[3] Responsibilities of researchers adapted from the Australian Code for the Responsible Conduct of Research. Part A – Principles and practices to encourage responsible research conduct. Australian Code

3.2 Scope

This policy is intended for research that is initiated and conducted by WH and its staff. Collaborative research will be subject to the research project administering institute's publication and authorship policy, which should ideally align with the terms set out by the Australian Code.
This policy applies to all WH employees, and other related staff, for the publication and authorship of research data that is generated as a result of a WH led collaboration, carrying out their WH research duties, or whilst acting on behalf of WH.
Employees, students and honorary affiliates of WH's academic partners will need to adhere to their institutional policy in how publication and authorship is to be managed for research conducted on behalf of their respective institution.

3.3 Procedure

3.3.1 Publication and dissemination of research finding

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 WH Intellectual Property Policy.

The following principles apply to publication of research findings:

i. Researchers must ensure that their research findings are accurate and are reported in a complete, correct and unambiguous manner.
ii. Negative results should be reported where possible.
iii. Potential conflicts of interest must be disclosed in accordance with the WH Conflict of Interest Policy.
iv. The same set or subset of data may not be published more than once, except where due reference is made.
v. Cite the work of other authors fully and accurately.
vi. Clinical trials should be registered with a recognised register in order to promote access to information about clinical trials

WH has an obligation to oversee confidentiality agreements to protect intellectual property rights between WH, the researcher and the sponsor of the research. WH will work with researchers and the sponsor to ensure that where such agreements limit free publication and discussion, an approved process is instigated to ensure that limitations and restrictions are explicitly agreed. Researchers are required to submit all confidentiality agreements to the Office of Research for review and approval before they are signed.

WH is committed to ensuring that sponsors of research understand the nature of academic freedom and that sponsors do not discourage publication or the dissemination of research findings for longer than the minimum time required.

Researchers must take great care when reporting research findings to the media. It would be preferable for such findings to have been subjected to peer review before reporting. The status of research findings, whether preliminary, complete, peer reviewed or otherwise must be explicitly disclosed. The WH Public Affairs unit may be able to assist with communication of research findings through the media and to the wider community through various channels (print and online, including social media), if it is deemed that the project warrants broader dissemination and publicity.

3.3.2 Authorship criteria

Attribution of authorship as defined by the International Committee of Medical Journal Editors (ICMJE) Defining the Role of Authors and Contributors is based on substantial contributions to:

i. Conception and design of the research described in the manuscript.
ii. Collection, analysis and interpretation of the research data.

iii. Drafting of the manuscript describing significant parts of the work, or critical revision of the manuscript so as to contribute to its interpretation.

Contributions to at least one of these three criteria are required to qualify as an author.

The right to authorship is not tied to either position or profession, and does not depend whether the contribution was paid or voluntary. A researcher's name would not normally warrant inclusion as an author in situations where their participation related solely to the acquisition of data, the acquisition of funding or where their role in the research related only to general overall supervision.

3.3.2.1 Collaborators

Collaborators should discuss authorship as soon as it becomes apparent that data obtained may be suitable for publication and the preparation of a manuscript is discussed. It is recommended the person drafting the manuscript list all authors first, and discuss the order of authors at a later stage.

3.3.2.2 Confirmation of authors

All persons who make substantial contributions as defined in above should be offered authorship. They then need to accept this offer and contribute as above to qualify for inclusion as an author at the time of submission. Persons who do not make substantial contributions should not be offered authorship. It may be appropriate to include them in acknowledgements. WH views inclusion favourably, but authorship must be justified in terms of contribution to the work and compliance with the Australian Code.

WH recommends a list of authors should be agreed first, using the criteria given above. Agreement on the order of authors would be a subsequent step. Often the first author will be the person who has had day-to-day responsibility for the strategic development of the research, problem solving, and writing the results section of the manuscript. The last author will often be more senior; perhaps a unit or department head that has set the strategic direction, outlined the project, and had responsibility for the introduction and conclusion sections of the manuscript.

3.3.2.3 Corresponding author

One of the authors is appointed "corresponding author" and is responsible for recording names of all authors and the role of each with respect to the manuscript. Details of anyone that is offered authorship but declines must be recorded in writing and this record is retained by the corresponding author.

i. All authors **must** have the opportunity to read the final manuscript before submission, and must sign the record indicating that they have had this opportunity and agree to the submission. Non-compliance with this step means that individual will be excluded from authorship. The corresponding author is required to complete an Author Certification Form with every manuscript submission
ii. The corresponding author must retain the Journal author sign off sheets and a copy of the manuscript.

3.3.2.4 Multi-centre trials

The ICMJE authorship and non-author contributors guidelines (referenced above) set out that multi-centre trials are increasingly being attributed to a group. All members of the group who are named as authors should fully meet criteria for authorship/non-author contributors.

The group should jointly make decisions about authors/non-author contributors before submitting the manuscript for publication. The corresponding author needs to be prepared to explain the presence and order of these individuals.

3.3.3 Author disputes

In the event of disagreement either on the list of authors, or on the order of authors, WH recommends that a meeting of all authors be held to discuss the matter. The senior researcher (Department Head; Principal or Professorial Research Fellow) not directly involved in the work in question may be invited to attend such a meeting if requested by any of those involved to provide an unbiased perspective.

If there are persistent serious disagreements concerning authorship of any paper, any of those involved have the right to appeal to the RPD (arbitrator), who can meet with all of those involved and offer arbitration. If the researchers involved are not able to resolve the matter, the WH Director of Clinical Research can decide the matter and need not take into account any input from any member who is personally involved. Where conflicts of interest require the member of the research directorate to withdraw from the decision, the Research Program Director, suitable academic Chair or appropriate member of the WH Low Risk Ethics Panel (LREP) may be called on to help resolve the impasse.

3.3.4 Acknowledgement of funding bodies

It is a condition of receipt of research funding that the funding source be acknowledged in any resulting publication. Most funding bodies have very specific wording requirements for attribution of funding source and the grant recipient should ensure that they familiarise themselves with these requirements.

Researchers must ensure that others who have made substantial contributions to the research and those individuals and organisations who have provided facilities or material are also appropriately acknowledged. The names of sponsors of research must be disclosed.

3.3.5 Attribution of collaborating institutions

Attribution of affiliations or honorary appointments should be listed as outlined by the collaborating institution which usually has a specified wording.

3.4 Steps for authors

3.4.1 Manuscript submission

i. Agree on publication type and journal
ii. Confirm contribution to manuscript satisfies WH Authorship criteria
iii. If criteria are not met consider acknowledgement of contribution
iv. If authorship is not preferred, refuse authorship in writing to the corresponding author
v. Those offered authorship must accept or decline in writing
vi. The executive or senior author must maintain signed acknowledgements of authorship for all publications.
vii. Index all data relevant to the publication and ensure it is stored securely and easily retrievable
viii. Review author responsibilities with respect to the journal to which the manuscript will be submitted
ix. Review and comment on manuscript when received from corresponding author
x. Complete and sign author declaration form if required by the journal and return to corresponding author

3.5 Additional steps for corresponding authors

3.5.1 Manuscript submission

i. Assign order of authors
ii. Circulate manuscript to all authors for review and comment
iii. Review and discuss colleagues' comments
iv. Circulate final version of manuscript to all authors for comment
v. Collect author sign off forms if required by the journal
vi. Send the original author sign off sheet(s) to the Journal

3.6 Intellectual Property

Ownership of intellectual property for research which may be initiated by Western Health, or conducted in collaboration with other research organisations or which is commercially sponsored, should be clearly defined by a Research Agreement that sets out the terms on Intellectual Property and how it will be allocated between the various parties engaged in the conduct of the research.

All researchers engaged in research on behalf of Western Health should familiarise themselves with the Intellectual Property and Moral Rights policy: P-GC7
Western Health researchers that are initiating research that involves other research organisations should use the WH Research Collaboration Agreement that clearly sets out the terms of the collaboration between the various entities.

Where a WH researcher is being asked to collaborate on a research project, the sponsor of the research may provide the Research Agreement. It is advisable that all nonWH standard approved agreements be reviewed and authorized by the Office for Researchprior to them being executed in accordance with the Western Health Delegation of Authority protocol. Non-standard agreements that have not been previously endorsed by WH legal services , may be sent to WH legal for further review.

WH Approved Agreements

1. WH Research Collaborative Agreement Template (Australia only and International Collaboration Templates available)
2. Medicines Australia Standard Clinical Trial Research Agreement(s)(CTRA)
3. Melbourne Academic Centre for Health (MACH) Research Collaboration Agreement
4. WH Memorandum of Understanding (MOU)

All commercially sponsored clinical trials should be conducted using the VMIA approved standard Clinical Trial Agreements which can be downloaded from the Medicines Australia website. Medicines Australia Clinical Trial Agreements

The type of Agreement to be used will be dependent on the type of trial being conducted. These standard Agreements has been pre-approved by the DHS and are acceptable to Western Health. Any amendments are made through either Schedule 7 or 4. The DHS has pre-approved schedule 7 and 4 clauses for particular sponsors. Any inclusions under these Schedules should be reviewed by the Office for Research.

3.7 Definitions

Arbitrator	An internal or external person appointed by the Institute experienced with the Code and able to assist with research authorship/publication disputes
Author	A person who has made a substantive intellectual contribution to a published study
Corresponding Author	The author responsible for corresponding with the journal and submitted author sign-off sheets
ICMJE	International Committee of Medical Journal Editors
NHMRC	National Health and Medical Research Council (grant funding body)
Non-author contributor	A person who fails to meet the definition of authorship but who provided financial, conceptual, instrumental-technical, moral, or editorial† assistance. Non-author contributors should be acknowledged, and their contributions specified.

3.8 Reference material

Organisation	Reference	Location
NHMRC/ARC	Australia Code for the Responsible Conduct of Research, 2018	Australian Code
ICMJE	Uniform requirements for manuscripts submitted to biomedical journals, Recommendation 2022	ICMJE
Medicine Australia Standard Agreements	To be used when WH is engaged by a commercial sponsor or any entity acting in this capacity	Medicines Australia Clinical Trial Agreements
WH	Research Code of Conduct 2023 - Conflict of Interest Procedure	See Section 6
WH	Collaborative Agreements (Funding and No Funding Template). Can be used when WH is the initiator of collaborative research.	Research Collaborative Agreements
WH	Intellectual Property and Moral Rights	Policy Guide P-GC7

4 Supervision of Students Undertaking Research

4.1 Key Principles

WH actively promotes the responsible conduct of research to trainees (both undergraduate and graduate students). Supervisors and students are required to meet their obligations under the WH Research Code of Conduct for Research and also engage in a broader dialogue about research integrity and the responsible conduct of research.

Heads of departments and supervisors of research students have an additional responsibility: to actively ensure that their staff and students have access to the WH Research Code of Conduct and other relevant information and advice to support their compliance with the requirements and to promote the highest of standards in research integrity.

Supervisors are responsible for ensuring training, mentoring and overseeing the research outcomes of students. In return, research trainees of WH are required to work with integrity and are also personally accountable for acting in accordance with the principles of the WH Research Code of Conduct. Trainees are responsible for seeking guidance and to complete their induction and training as soon as practicable.

The Research Supervisors must seek to ensure the validity of research data obtained by a research trainee under their supervision.

Research Supervisors must take responsibility for overseeing all stages of the research process, including developing a hypothesis or research objective, preparing applications for funding, selecting methods for research and data collection and recording, and summarising, analysing and reporting findings.
Research Supervisors must not exploit research students and junior colleagues. Research Supervisors must not put research students or junior researchers at risk. Risks can include chemical hazard, infectious disease and psychological trauma..
Students of WH Academic partners should be made aware of the WH Research Code of Conduct and familiarise themselves with the elements that are relevant to their conduct of research on WH premises or utilising WH resources. Students of WH's academic partners undertaking research as part of their training program are the

responsibility of the University (a.k.a Academic partner) and therefore the University's Code of Conduct policies and procedures will apply once a research incident is identified. A supervisory agreement should be completed prior to commencement of training program/candidatures.

5 Collaborative Research

5.1 Introduction

WH has established a strong reputation for excellence and the highest standards of integrity in research.

Collaboration with researchers employed by other institutions is a regular feature of contemporary research.

WH requires that arrangements for collaborative research projects are agreed before a project begins and are formalized in writing through a Research Collaboration Agreement or mutually acceptable document. All research agreements must be reviewed by the Office for Research and executed by the assigned authorised delegate. Agreements which deviate from the standard template agreements on offer may be subject to review by the WH legal department.

5.2 Scope

This policy applies to all WH employees, and other related staff for their involvement in collaborative research. When in doubt as to the type of Research Agreement to be used for collaborative studies, the researcher should seek the guidance of the WH Office for Research. WH has in place a standard research collaborative agreement that can be used for all collaborations initiated by Western Health.

5.3 Procedure

5.3.1 Agreement between researchers

Agreements to collaborate on research projects usually evolve over time.

Initial discussions are usually informal and conducted between researchers about the unique knowledge, expertise, techniques, methods or resources such as samples that each party can bring to a proposed project.

Objectives, contributions, time lines and a detailed research plan are refined in the process of applying for funding.

Where a WH researcher agrees to be an investigator on a collaborative project, he or she agrees by implication to formalise the collaboration through a written agreement if and when the project secures funding.

Before accepting a grant, researchers must, as a minimum, consider and agree on the following issues prior to execution of a formal Multi-Institutional Agreement (MIA) for NHMRC funded collaborations, or a Research Agreement applicable to other collaborations:

i. Financial management;
ii. Intellectual property;
iii. Authorship and publication;
iv. Consultancies;
v. Secondments;
vi. Ethics approval;
vii. Safety clearances;
viii. Regulatory compliance; and
ix. Ownership of equipment, research data and primary materials.

The relevant type of agreement must be executed for **each** project with organisations where there is a transfer of funds between the administering organisation and collaborating organisations. The agreement is a legal contract which must be executed by the parties to the agreement before the project can proceed.

For the WH participation in the collaboration, the agreement must be signed in accordance with the WH Delegation of Authority. The Research Program Director, Chief Medical Officer or Chief Executive Officer and Board of Directors are the nominated delegates.

WH researchers should not, under any circumstances, make any commitment to expend funds until the MIA and research agreement have been executed.

5.4 Conflict of interest

Researchers must disclose in writing to the RPD as soon as possible any actual or perceived conflict of interest relating to any aspect of the collaborative research project.

Refer also to Conflict of Interest Policy contained within Section 6 of this document.

6 CONFLICT OF INTEREST

6.1 Introduction

WH has established a strong reputation for excellence and the highest standards of integrity in medical research, teaching and management.

Effective declaration and management of conflicts of interest is an essential element of maintaining integrity for researchers and for WH alike. WH Researchers should complete and submit an annual "Declaration of Interest" Form to ensure that any potential conflicts of interest are identified early on and managed accordingly.
This policy must be read in conjunction with WH's overarching Conflict of Interest policy, Procedure code OP-RS2.

6.2 Scope

This policy covers all WH employees, students hosted at WH, visitors and adjunct appointees such as honorary members of WH's academic partners.

For staff with dual or multiple appointments, the policy of the institution that owns the research or activity, or majority share thereof, that the conflict relates to will apply upon agreement between the relevant parties.

6.3 What is 'Conflict of Interest'?

Conflicts of interest in research include any circumstances where a researcher has a real, perceived or potential opportunity to prefer his / her own interests, or those of another person or organisation, to the interests of WH.

Real or perceived opportunities to give preference to personal interests arise from competing obligations and can be other than financial.

Examples of conflicts of interest in research include but are not limited to situations:

i. Where the research is sponsored by a related body[4];

[4] A related body is any person or body with which the researcher has an affiliation or a financial involvement.

A financial involvement includes a direct or -> indirect financial interest, provision of benefits (such as travel and accommodation) and provision of materials or facilities.

An indirect financial interest is a financial interest or benefit derived by the researcher's relatives, personal or business associates, or research students.

ii. Where the researcher or a related body may benefit, directly or indirectly, from any inappropriate dissemination of research results (including any delay in or restriction upon publication of such results);
iii. Where the researcher or a related body may benefit, directly or indirectly, from the use of WH's resources;
iv. Where the researcher conducts a clinical trial, which is sponsored by any person or organisation with a significant interest in the results of the trial.
v. Where private benefits or significant personal or professional advantage are dependent on research outcomes.

A conflict may compromise, or have the appearance of compromising, a researcher's professional judgment in conducting, evaluating or reporting on research. It may affect, or be seen to affect, the collection, analysis and interpretation of data. It could also impact on hiring of staff, procurement of materials or equipment, sharing of results, choice of licensees, choice of protocol, involvement of human subjects, and the use of statistical methods.

6.4 Managing Conflicts of Interest

The responsibility for managing a conflict of interest rests, in the first instance, with the individual. The guiding principles for managing Conflict of Interest situations are that:

1. Actual and / or perceived conflicts are to be avoided;
2. Early and full disclosure of any conflicts is required;
3. The Office for Research will determine a management plan for conflict of interest situations in consultation with the affected researcher.

WH recognises that conflicts can arise at any stage in a research project or program and that it is not always possible to predict and declare a conflict at the outset of a project. The important issue is that disclosure has to be made at the earliest opportunity when it is identified that a potential for a conflict of interest may develop or has occurred.

6.4.1 Disclosure

A researcher must make a full disclosure of a conflict of interest or of circumstances that might give rise to a perceived or potential conflict of interest as soon as reasonably practicable to:

i. His/her Unit or Dept. Head (in the majority of cases in WH, this will be the direct supervisor or line manager);
ii. In the case of a Unit or Dept. Head, to the RPD or DCR;
iii. In the case of the RPD or DCR, to the Chief Medical Officer (CMO) who may at his/her discretion decide to inform the CEO and/or Board of Directors.

For the conduct of clinical trials, full disclosure must include the nature of the sponsorship and the relationships between the sponsor, trial subjects and the clinical investigator.

The RPD is the senior member accountable for managing Conflict of Interest in research within WH.

6.4.2 Handling of disclosures

Disclosures to be handled as follows:

i. The officer in receipt of a disclosure must discuss the matter with the staff member concerned to determine a procedure for the management or elimination of the conflict of interest. The agreed procedure must be documented. The researcher will receive a copy of the agreement and a copy will be placed on record by the WH Office for Research;
ii. A researcher must comply with the procedure agreed as set out above in *(i)* in relation to the management of the conflict of interest;

iii. It is the responsibility of Unit/Dept. Heads to ensure that conflicts of interest in research involving members of their research groups are managed appropriately and to observe the requirements of this policy and procedure in relation to their own work and research conduct;
iv. Any WH researcher who is affiliated with, or has a financial interest in, any organisation with a direct commercial interest in WH research must disclose this in writing. The CMO of WH, acting on advice from a Unit Head and/or the RPD is entitled to direct a researcher to discontinue an established affiliation that is deemed inappropriate.
v. It is WH's strong preference that researchers engaged in clinical trials do not have any financial interest in the outcome of the trials (for example a significant equity interest or an executive position in a company commissioning the research) which would render them vulnerable to allegations of lack of objectivity.

6.5 Resolution process

Where the officer in receipt of the disclosure is unable to resolve the Conflict of Interest, the matter will be escalated to the RPD who will meet with the individual(s) involved to agree on a Conflict of Interest management or elimination plan.

Where the RPD is unable to resolve the Conflict of Interest, the matter may be referred in the next instance to the CMO, if only external parties will be able to achieve a resolution.

At all times the management of Conflict of Interest must be in accordance with the WH Conflict of Interest Procedure OP-RS2

6.6 Reporting to a granting body

Where the Conflict of Interest has arisen during research sponsored by a granting body, the RPD or his/her delegate (typically the Manager, Office for Research) shall notify the relevant granting body and take such steps that the granting body may reasonably require to resolve or otherwise deal with the Conflict of Interest.

6.7 Research-related committees

i. Members of a research-related committee shall declare any Conflict of Interest related to the activities being considered by that committee to the Chair of that committee;
ii. Members of a research related committee shall refrain from involvement in the decision-making process in matters in which they have a Conflict of Interest. This may involve exclusion from the meeting or exclusion from some or all of the committee's activities;
iii. Conflict of Interest declarations will be recorded and should include information on how the conflict was/is managed in the proceedings

6.8 References

WH Conflict of Interest policy OP-GO2.1.3

7 Breaches of the Code, Research Misconduct and Framework for Resolving Allegations

7.1 Research misconduct

Research misconduct does **not include** honest differences in judgment in management of the research project, or honest errors that are minor or unintentional.

A complaint or allegation relates to research misconduct if it involves all of the following:

i. An alleged breach of the Code;
ii. Intent and deliberation, recklessness or gross and persistent negligence;

iii. Serious consequences, such as false information on the public record, or adverse effects on research participants, animals or the environment.

Breaches of the Code will require specific action by supervisors and RPD, DCR and Manager from Office for Research at 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 of the Code may also constitute research misconduct, and will be considered as such where these have been the subject of previous counselling or specific direction.

Examples of research misconduct include, but are not limited to:

i. Fabrication of results
ii. Falsification or misrepresentation of results
iii. Plagiarism
iv. Misleading assignment of authorship
v. Failure to declare and manage serious conflicts of interest
vi. Falsification or misrepresentation to obtain funding
vii. Conducting research without ethics approval as required by the National Statement on Ethical Conduct in Research Involving Humans and the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes
viii. Risking the safety of human participants, or the wellbeing of animals or the environment
ix. Deviations from the Code that occur through gross or persistent negligence
x. Wilful concealment or facilitation of research misconduct by others.

WH regards any incident involving proven scientific misconduct as serious, and will take appropriate action. Such actions may include dismissal in accordance with WH 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.

7.2 Confidentiality

Allegations of research misconduct can be extremely serious for the individual/s concerned and their home institute. A proven case of research misconduct may end a research career. It may also cause substantial reputational damage to the host institution and impact on viability of collaborations, competitiveness for funding and community support. Reputational damage to an individual or to WH cannot be undone once an allegation has become common knowledge.

Given the potential for extreme consequences, it is imperative that strictest confidentiality is observed by everyone who is party to an allegation and investigation into research misconduct. In particular, the identity of the person subject to the allegation needs to be protected in the course of initial investigation while the facts and merits of a case are being established. The identity of a complainant will also be protected.

Confidentiality is not the same as anonymity. Anonymous complaints are not encouraged and may not be investigated if they raise concerns over a lack of procedural fairness.

7.3 Purpose

To clearly set out how to report an allegation of research misconduct and the procedure for handling Research Misconduct allegations within WH.

7.4 Scope

All research staff, scientists, clinicians and students of WH who do not hold a fractional salaried appointment with any of WH's academic partners.

For staff with dual or multiple appointments, the policy of the institution that owns the research or activity, or majority share thereof, that the breach or misconduct relates to will apply upon agreement between the relevant parties.

7.5 Procedure

7.5.1 Reporting research misconduct

WH expects any staff member or student who believes that research misconduct may have occurred to bring this to the attention of management in a timely manner.

It should be noted that disputes and disagreements over authorship are quite common, while other kinds of research misconduct are relatively rare.

In the first instance, an informal and confidential approach to either the RPD or DCR would be appropriate. Following consultation with one of the nominated positions above; one option is to raise an allegation in writing with the Designated Person (DP).

7.5.2 Designated Person

The Designated Person (DP) is a senior member at WH who is experienced in research and research management. The role of the DP is to advise the CMO whether allegations appear to be justified and whether a *prima facie* case exists.

The Research Program Director is WH's DP for handling research misconduct allegations or if not available or otherwise conflicted, the Director of Clinical Research can be approached.

Allegations of research misconduct or breaches of the Australian Code or WH Research Code at WH 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 his/her delegated officer. The DP must maintain full records of all matters that relate to allegations of research misconduct.

If an allegation concerns the DP(s), the person raising the allegation should consult an Adviser in research integrity in the first instance, who can advise on where such an allegation should be directed. [i.e.: Chair or Deputy Chair, or Audit and Risk Committee]

Receipt of allegation of research misconduct

All allegations of research misconduct are taken seriously and responded to promptly.

Designated Person preliminary investigation

Where an allegation of a breach of the WH Research Code or research misconduct is received, the WH DP will initially consult with the WH Human Resources Officer to establish whether the researcher who is the subject of the allegation is employed solely by WH, or holds a conjoint appointment with any of WH's onsite academic partners.

Where a staff member subject to an allegation of research misconduct holds a part-time appointment with any of WH's any academic partners and the allegation pertains to a project that is collaborative in nature, the WH DP will contact their University respective contact and work with the appropriate University officers to further investigate the allegation and determine who and how the matter will be managed from here on.

The WH DP will deal with allegations involving researchers who are employed only by WH. Where an academic partner may also have a vested interest in a research allegation, agreement between the two parties should be reached on which entity will manage the process. This should be underpinned around the nature of the allegation and who is best resourced and experienced to manage the nature of the allegation on behalf of all interested parties. The DP will undertake a preliminary investigation and provide a report to the CMO to advise whether in the DP's opinion:

i. The allegation involves a breach of the WH Research Code due to lack of intent or seriousness: in this case the DP report will provide recommendations to ensure the issue is corrected and to reduce the likelihood of any recurrence; or
ii. A *prima facie* case of Research Misconduct exists:
    - If the Research Misconduct is not admitted by the relevant person, then the DP report will include a recommendation for a research misconduct inquiry by an Internal or External inquiry panel;
    - If the allegation involves a collaborative team with researchers from another institution, and/or a student enrolled at a University, the investigation and inquiry may involve more than one institution; in such cases the DP is responsible for ensuring appropriate coordination if WH agrees to assume the lead management role of the allegation process.

    The DP report should also include any recommendations to ensure the issue is corrected and to reduce the likelihood of any recurrence; or
iii. No breach of the WH Research Code (including research misconduct) has occurred and the allegation(s) should be dismissed.

On receipt of the DP report, the CMO must decide whether to accept the advice and how to proceed. WH may nominate a person to the role of Assistant DP who will provide support and assistance to the DP in the process of conducting the preliminary investigation.

7.5.3 Internal or external research misconduct inquiry

An Inquiry is used to examine the evidence and make a judgment on whether Research Misconduct has occurred.

The RPD will decide whether an Internal or an External Inquiry is appropriate, in accordance with the requirements set out in the WH Research Code of Conduct.

The Inquiry panel is generally composed of senior researchers and professionals familiar with the WH Research Code of Conduct, and all members must be free from bias or conflicts of interest.

i. WH may draw on external expertise as required for membership of an internal inquiry panel.
ii. The person/s responding to the allegations may have a support person attend the Inquiry with him/her/them.
iii. Legal representation is only allowed in an independent External Inquiry.
iv. Panel members who conduct an independent External Inquiry must not be employed by WH, have other current or recent dealings with the WH or otherwise be subject to a reasonable perception of bias.

The Inquiry panel advises the RPD of the findings and whether Research Misconduct has occurred. Where the Inquiry panel has found that Research Misconduct has occurred ("Proven Research Misconduct"), it may include recommendations to the RPD on disciplinary actions and scientific remedies, provided that the decision on actions and remedies will be made by the RPD in the RPD's absolute discretion (having appropriate regard to the WH Employment Agreement and relevant laws).

7.5.4 Notifications and remedies

In accordance with the WH Research Code, the RPD must inform all relevant parties, including affected staff and collaborators at other institutions, of the outcome of an investigation into an alleged breach of the WH Research Code, including research misconduct inquiry findings, and the actions taken by the Institute.

i. Journal co-authors and journal editors will require notification if a retraction is required.

ii. Funding bodies require notification of grants which may be affected, for example the NHMRC requires notification of the decision from any preliminary investigation or formal inquiry into any alleged Research Misconduct, whether conducted internally or independently, and reasons for that decision within ten (10) working days of reaching that decision.

The RPD will decide what disciplinary actions and scientific remedies are required in cases where a breach of the Code or Proven Research Misconduct have been established, in accordance with the WH Employment Agreement and Disciplinary Policy and relevant law, and the action taken will depend on the seriousness of the misconduct and the surrounding circumstances.

Possible disciplinary actions for a Breach of the WH Research Code that does not constitute Research Misconduct include:

i. Counselling or advice;
ii. Increased supervision of future research;
iii. Written warnings;
iv. Demotion; or
v. Any other action deemed necessary in the circumstances.

Possible disciplinary actions for Proven Research Misconduct include:

i. Written warnings;
ii. Demotion;
iii. Reduction of pay;
iv. Partial suspension;
v. Termination of employment; and/or
vi. Any other action deemed necessary in the circumstances.

An established Breach of the WH Research Code or Proven Research Misconduct will be recorded on the personnel file of the person involved.

Scientific remedies may involve journal retractions to correct the public record and notifications to funding bodies.

Careful review of subsequent work, and work practices is recommended.

If allegations are shown to be unfounded, WH will make every effort to reinstate the reputation of the accused researcher. If allegations are shown to be vexatious or mischievous, complainants who are employees of WH will face appropriate disciplinary action in accordance with the WH Disciplinary Policy.

7.6 Steps for raising an allegation

7.6.1 Advisers in Research Integrity

Discuss your concerns with the most appropriate person:

i. your supervisor;
ii. your research Unit Head and/or
iii. WH designated person (DP): WH Research Program Director (RPD)or the Director of Clinical Research (DCP)

7.7 Investigation by Designated Person

7.7.1 Steps

i. Issue of concern or allegation is reported to the DP in writing.
ii. NHMRC, or other funding body, as appropriate, notified of the receipt of an allegation of Research Misconduct (within 10 working days).
iii. Communication between DP and the person raising allegation, if known.
iv. If the allegation is reported anonymously, the documentation provided is reviewed.
v. Meeting of DP and person the allegations are against.

vi. DP investigate the issues, including interviewing any other people who may have relevant information, reviewing primary data and any other appropriate actions.
vii. DP prepares a report on the Preliminary Investigation for the Chief Medical Officer in accordance with section 2.5 of the Procedures and the WH Research Code with findings and recommendations.

7.8 Decision by Chief Medical Officer

7.8.1 Steps

i. Chief Medical Officer reviews advice, decides whether to accept the advice and how to proceed.
ii. If relevant, appropriate Executive Director is also contacted.
iii. NHMRC, or other funding body, as appropriate, notified of the decision resulting from the Preliminary investigation (within 10 working days)

7.9 Definitions

Allegation	An unproved assertion
Breach	Failure to observe the "Australian Code", minor deviation
Misconduct	Improper professional behaviour
Research Misconduct	Improper behaviour which can include plagiarising, fabricating or altering data with the intent to mislead; denying authorship when a person meets the criteria or "honorary" authorship when authorship is given but does not meet authorship criteria. Serious breach of the "Australian Code".
Designated Person (DP)	A senior member of the Institute experienced in research and research management. [NB: The Designated Person at WH is the Research Program Director]
Advisor in Research Integrity	Senior staff (internal and external) nominated by the Institute to be an advisor of research integrity ("advisors").

7.10 References

The University of Melbourne	The University of Melbourne Research Integrity
Deakin University	Deakin University Research Integrity
Victoria University	Victoria University Research Integrity

8. Associated Policies and Procedures

For the purpose of ensuring that the most current WH policies applicable to this document can be accessed, below are their respective links.

All staff undertaking research at or on behalf of Western Health should familiarise themselves with the below WH policies.

1. WH Code of Conduct P-GO2.2
2. Honorary Appointments OP-EP1
3. Reporting of Professional Misconduct OP-HR3.3.3
4. Disciplinary Procedure: OP-HR5.2.1
5. Intellectual Property and Moral Rights: P-RE2.1
6. Research and Ethics P-RE1.1

9 APPENDICES

9.1 Roles and Responsibilities for a Multi-site Research Project

Coordinating Principal Investigator (CPI)	• Is appropriately clinically qualified and experienced to conduct the clinical trial • Responsibilities include: ◦ overall clinical conduct of the research project at all sites approved by the reviewing Human Research Ethics Committee (HREC) ◦ medical care and supervision of participants ◦ submission of the ethics application to the reviewing HREC's research office ◦ ongoing communication with the reviewing HREC's research office ◦ dissemination of information from the HREC to site Principal Investigators, sponsor, and project/trial coordinator ◦ creation of a site-specific assessment (SSA) form for each participating site and transferring it to the site Principal Investigator • Is thoroughly familiar with the research protocol and the investigational product(s) • Is compliant with Good Clinical Practice (GCP) (if applicable to the research project) and regulatory requirements • Is the Principal Investigator for their own site • May delegate some duties to appropriately qualified and experienced staff, but remains responsible
Principal Investigator (PI)	• Is appropriately clinically qualified and experienced to conduct the clinical trial at the site • Responsibilities include: ◦ clinical conduct of the research project at the site ◦ medical care and supervision of participants at the site ◦ provision of site-specific documents* (as required) to the CPI for inclusion in the ethics application ◦ submission of the research governance/SSA application to the site research governance officer (RGO) ◦ ongoing communication with the site RGO • Is thoroughly familiar with the research protocol and the investigational product(s) • Is compliant with Good Clinical Practice (GCP) (if applicable to the research project) and regulatory requirements • May delegate some duties to appropriately qualified and experienced staff, but remains responsible

Associate Investigator (AI)	• Is appropriately clinically qualified and experienced to undertake duties in the research project • Is thoroughly familiar with the research protocol and the investigational product(s) • Is compliant with Good Clinical Practice (GCP) (if applicable to the research project) and regulatory requirements • Performs research project duties as required, but does not have authority for the site or research project
Sponsor	• Carries the medico-legal responsibility associated with the conduct of a research project (e.g. agreements, insurance, indemnity) • Usually initiates, organises and supports management of a research project • May be an institution, investigator, collaborative group or commercial company • Must be an Australian entity • Is responsible for safety monitoring and reporting to the reviewing HREC in Victoria • Is responsible for post-approval reporting to the reviewing HREC in Victoria

*A list of Site-specific documents is available on WH Research and Governance Website

Detailed information is available at https://www2.health.vic.gov.au/about/clinical-trials-and-research.

9.2 Monitoring and Reporting

Report	CPI Responsibility	PI Responsibility	Sponsor Responsibility
Safety report	• Communicate with sponsor • Communicate with PI(s) • Sign report	If safety event occurs at own site: • Notify CPI, sponsor and site RGO If safety event occurs at another site: • Communicate with site RGO	• Submit **Safety report** to reviewing HREC's research office • Communicate with HREC, CPI/PI/trial coordinator
Annual safety report form (interventional clinical trial only)	• Communicate with sponsor • Communicate with PI(s) • Sign report	• Communicate with site RGO	• Submit **Annual safety report form** to reviewing HREC's research office • Communicate with HREC, CPI/PI/trial coordinator
Amendment request form	• Communicate with sponsor • Communicate with PI(s) • Sign form	• Communicate with CPI • Communicate with site RGO – research governance/SSA amendment may be required	• Submit **Amendment request form** to reviewing HREC's and RGO's research offices • Communicate with HREC, RGO, CPI/PI/trial coordinator
Progress report – project form (HREC)	• Communicate with sponsor • Communicate with PI(s) • Sign report	• On request, notify sponsor of site information •	• Submit **Progress report – project form** to review HREC's and RGO's research officesCommunicate with HREC, RGO, CPI/PI/trial coordinator

Project final report/Site closure report	• Communicate with sponsor • Communicate with PI(s) • Sign report	• On request, notify sponsor of site information • Communicate with site RGO	• Submit **Project final report/Site closure report** to reviewing HREC's research office • Communicate with HREC. RGO. CPI/PI/trial coordinator
Protocol deviation or violation report	• Communicate with sponsor • Communicate with PI(s) • Sign report	• Notify sponsor of occurrence of protocol deviation or violation • Communicate with site RGO	• Submit **Protocol deviation or violation report** to reviewing HREC's (serious) and RGO's (non-serious) research offices • Communicate with HREC (serious), RGO (non-serious), CPI/PI/trial coordinator
Progress report – site form (RGO)	N/A	• Submit **Progress report – site form** to site RGO	N/A
Site audit report for research	N/A	• On request, submit **Site audit report for research** to site RGO	N/A
Complaint report	• If notified of complaint by PI, forward to sponsor and reviewing	• Submit **Complaint report** to site RGO	• Record the complaint

Monitoring and reporting information (Victoria) is available at https://www.clinicaltrialsandresearch.vic.gov.au/monitoring-and-reporting

9.3 Classification and Requirements For Research Conducted On WH Campuses: Governance Approval Guidelines

WESTERN HEALTH RESEARCH	WCHRE ACADEMIC PARTNER RESEARCH (UOM & VU)	COLLABORATIVE AND INDUSTRY SPONSORED RESEARCH
Research will be Classified and/or Acknowledged as Western Health when: 1. The study protocol is owned by Western Health and WH is study sponsor and ultimately owns the research Intellectual Property 2. WH is the named entity on the CTN notification to the TGA **Requirements:** 1. The PI must be an employee of WH (*Honorary appointees can't fulfil this requirement for studies that require TGA notification. For non TGA notifiable interventions this will be a case by case assessment by the office for Research.)* 2. WH must be identified as the sponsor and site of the study (*excluding commercially sponsored trials*) 3. Non WH employed researchers involved in the research with access to patients and/or their data, or need to use WH equipment must have an honorary appointment 4. WH is the primary entity acknowledged in publications and other media platforms as agreed between the parties **Honorary Appointments:** Non WH employees conducting research/diagnostic related investigations on WH patients must have a researcher and/or clinical honorary appointment to carry out these activities on WH patients Where WH is the investigating site, Honorary appointments will only be provided in accordance with clause 7.8 Limitations of the WH Honorary Appointment policy. Researcher honorary appointments are for a specific project and cannot be assumed to apply on other projects without authorisation from the Office for Research An honorary appointment application is not required if the project does not involve access to WH patients and/or their data or use of WH resources.	**Research will be Classified and Acknowledged as Research of a WCHRE Academic Partner when:** 1. The study protocol is owned by the WCHRE academic partner and/or: a. All aspects of the research will be conducted by staff and resources of the academic partner b. The research does not involve access to WH patients or their data c. Research participants are recruited directly from the community, and; i. are not deemed WH patients in any capacity ii. are not recruited into a WH study iii. are not recruited from any WH clinic 2. Research is laboratory based utilising WCHRE facilities and fully supported by the academic institute **Requirements:** 1. Ethics approval and governance authorisation approval is the sole responsibility of the academic partner initiating and conducting the research 2. Notification to the WH Office for Research of projects being conducted on site at WCHRE involving community human subjects	**Collaborative* Research is defined as research whereby:** 1. WH has engaged or has been engaged as a collaborating institute in the conduct of research initiated by another entity. **Requirements:** 1. For commercially sponsored or investigator initiated trials involving patients, WH is identified as the study site: a. the PI must be an employee of WH b. study sponsor must be an Australian legal entity c. trial arrangements are to be agreed exclusively between the sponsor and WH 2. An Australian legal entity can assume the role of Sponsor for Investigator initiated trials 3. All clinical trial obligations that are assigned to WH as study site, need to be executed by WH staff unless otherwise agreed to by PI and WH Divisional Director and in accordance with clause 7.8 Limitations of the WH Honorary Appointment policy. 4. All collaborative research must: a. Be ethically approved b. Have Site Specific Authorisation from WH c. Have an Agreement in place that defines the terms of the collaboration d. Acknowledges WH in publications and other media platforms as appropriate WH Governance approval is required if the study will be utilising WH resources or services or where WH is a collaborating institute / Study site Research involving Western Health patients and/or their data is to be conducted in collaboration with Western Health. When the research is involving Western Health patients, Western Health will be the investigating site and provide the PI and related study resources . A suitable research agreement must be in place. Student Research involving WH patients or their data (*excl Scholarly Selective students*): 1. Student must have a WH supervisor /sponsor 2. Student must have a research supervision agreement with supervisors.

WESTERN HEALTH RESEARCH CODE OF CONDUCT DECLARATION

I, ……, have read and agree to
(PLEASE PRINT NAME)
comply with the Western Health Research Code of Conduct (2023)

Signature: _____

Date: _____