

OFFICE FOR RESEARCH NON-CLINICAL POLICY

RESEARCH POLICY

Staff this document applies to:

- All Austin Health staff including honoraries
- All visitors involved in research associated with or supported by Austin Health, including fellows, scholars and students

Related Austin Health policies, procedures or guidelines:

- [Patient Safety & Clinical Excellence Framework](#)
- Research Misconduct Procedure
- Research Authorship & Outputs Policy
- Research Data Management Policy
- [Radiation Safety Policy](#)
- [Code of Conduct Policy](#)
- [Conflict of Interest Policy](#)
- [Gifts, Benefits and Hospitality Policy](#)
- [Fraud, Corruption Control and Other Losses Policy](#)
- [Code of Conduct Policy](#)
- [Conflict of Interest Policy](#)
- [Gifts, Benefits & Hospitality Policy](#)
- [Financial Management Policy](#)
- [Delegations of Authority Policy](#)
- [Fraud, Corruption Control & Other Losses Policy](#)
- [Public Interest Disclosure Policy](#)
- [Consent Policy](#)
- [Public Interest Disclosure Policy](#)
- [Public Interest Disclosure Procedure](#)

Key points:

- **Part A:** Roles and responsibilities
- **Part B:** Institutional oversight
- **Part C:** Research governance
- **Part D:** Project design
- **Part E:** Training & credentialing
- **Part F:** Feasibility assessment
- **Part G:** Equipment & materials
- **Part H:** Insurance & indemnity
- **Part I:** Intellectual property, commercialisation, and research data management
- **Part J:** Legal & contract administration
- **Part K:** Finances
- **Part L:** Ethics and site-specific approval

- **Part M:** Risk management, mitigation and regulatory oversight
- **Part N:** Monitoring & auditing
- **Part O:** Complaints handling
- **Part P:** Reporting
- **Part Q:** Study completion & archiving
- **Part R:** Research partner principles – research funds
- **Part S:** Research partner principles – research involving Austin Health patients, staff, data and biospecimens
- **Part T:** Research involving the use of animals for scientific purposes
- **Part U:** Institutional Biosafety Committee (IBC) for research involving genetically modified organisms.

Scope

This Policy states the requirements for the attribution and management of research in line with criteria set out in the [Australian Code for the Responsible Conduct of Research \(2018\) \(the Code\)](#) and [The National Clinical Trials Governance Framework](#) (The Australian Commission on Quality & Safety in Health Care, 2022).

This policy and associated procedures cover research which can reasonably be regarded as the responsibility of Austin Health whereby Austin Health is acting as a site and/or initiating the research.

The requirements outlined in this policy and its associated procedures, include best practice principles consistent with existing regulations for the conduct of clinical research in Australia. It also outlines how Austin Health meets its mandatory accreditation requirements under the National Clinical Trials Governance Framework.

Purpose

The purpose of this policy is to provide a clear outline of the sets of relationships and functions established by Austin Health, to ensure best practice is followed by using existing corporate and clinical governance structures. This policy will therefore outline the following:

- Governance, leadership and culture
- Patient safety and quality improvement systems
- Clinical performance and effectiveness
- Safe environments for the delivery of care
- Partnering with consumers
- Quality of clinical research, including design, review, feasibility, management, and transparency of quality indicators
- Risk and proportionality, including accountability to community for the use of funding, skills and resources
- The assessment of risk and feasibility to Austin Health, resources, research participants and community
- Accountability and transparency, including compliance with relevant legalisation to meet national and international standards, good stewardship of clinical research provision, appropriate training, skills, professional development, clinical competencies and organisational delegations
- Collaboration with collaborative groups, Medical Research Institutes, Universities and Sponsors of Clinical Research
- sponsors of clinical research
- Equitable access to sponsored and investigator initiated clinical research to meet the needs and priorities of Aboriginal & Torres Strait Islander peoples, consumers from different demographic locations and culturally diverse backgrounds.

Part A – Roles and Responsibilities

The Patient Safety & Clinical Excellence Framework outlines roles and responsibilities of the Austin Health Board, executives, managers, clinical and non-clinical staff. There is no difference in roles or responsibilities for the purposes of research. At a project level, guiding principles which specify that the research team must be suitably qualified and trained to perform their role, remains the same for all clinical care.

The Office for Research has been delegated by the Austin Health Board to fulfill the Institutional Roles and Responsibilities under the Australian Commission on Safety and Quality in Health Care's (ACSQHC) National Safety and Quality in Health Services (NSQHS) Standards, which incorporates the National Clinical Trials Governance Framework:

- NHMRC Australian Code for Responsible Conduct of Research
- NHMRC National Statement on Ethical Conduct of Research in Human Research
- NHMRC Australian code for the care and use of animals for scientific purposes
- International Conference Harmonisation in Good Clinical Practice (ICH-GCP)
- Any other relevant national and/or internal codes, legislation and guidance.

Key to these responsibilities is to set-up governance systems that embed research as a core health service business, by:

- Outlining the set of relationships and functions established by Austin Health, the Department of Health, governing body, executive, workforce, patients, consumers, and other stakeholders to ensure good research service provision; and
- Ensuring research service governance is an integrated component of the corporate and clinical governance at Austin Health. This ensures that everyone, including frontline investigators undertaking clinical trials or other research and members of governing bodies, such as Committees and Boards, are accountable to patients and the community. It also provides assurance that the delivery of research is of high quality, integrated into clinical care and continuously improving.

Part B – Institutional oversight

- (1) Institutional oversight of research is managed via the following corporation and clinical governance mechanisms:
 - a. Via the Office for Research to meet The Commission on Health Quality and Safety Accreditation standards This includes commercially sponsored monitoring reports submitted to the Research Steering Committee for review.
 - b. Safety reports will be submitted to the Office for Research per requirements outlined on the website. Aggregated safety reporting and risk profiles will be submitted to the Research Steering Committee for review.
 - c. Divisional Safety, Quality and Risk meetings must include relevant standing items to ensure oversight of research within their division. This includes financial management, workforce management and training, project feasibility, research infrastructure, safety reporting within the division, research audit and monitoring, progress against local strategic and business plans. Divisions are advised to refrain from developing separate research safety, quality and risk committees, instead the same clinical and corporate governance oversight should be applied to research.
- (2) The Office for Research will prepare and submit institutional reports to Austin Health Research Steering Committee, Executive and Board. This office will also be responsible for preparing and submitting institutional annual reports of ethics and governance committees to regulators, Department of Health and the Australian Commission on Safety and Quality in Health Care.

Part C – Research Governance

- (3) Research Governance is defined as the set of relationships and functions outlined in this policy, to ensure best practice is maintained during the design, planning, managing and delivery of clinical research studies and services. For avoidance of doubt, research governance is not considered to be a single form or role within the organisation. Forms such as the Site-Specific Assessment acts as a tool to assist in review but is not considered to be adequate oversight or documentation. Austin Health no longer has a Research Governance office or officer. This is because Austin Health uses existing clinical and corporate governance principles for oversight of research governance.
- (4) Austin Health Patient Safety, Quality and Excellence Unit has delegated responsibility for oversight of research and the National Clinical Trials Governance Framework to the Office for Research. The relationship between the Office for Research and the Austin Health Patient Safety, Quality and Excellence Unit is outlined in the Patient Safety & Clinical Excellence Framework.

Part D – Project design

- (5) All research must be designed to comply with [NHMRC National Statement on Ethics Conduct in Human Research](#) (2017, as updated), the [NHMRC Australian Code for the Responsible Conduct of Research](#) (2018) applicable legalisation, guidelines and local policies. For drug and device trials, research must also comply with [Therapeutic Goods Administration Guideline on Good Clinical Practice](#) (published 25 June 2018). Where there is conflicting advice, the National Statement should take precedence.
- (6) All reasonable efforts must be made by sponsors and/or researchers to design a project with consumer involvement, from concept through to delivery. Consumers should be relevant to the target population, and where possible, have lived experience.
- (7) All reasonable efforts must be made by sponsors and/or researchers to design a project which doesn't not specifically exclude culturally and linguistically diverse communities.
- (8) All reasonable efforts must be made to use the principles of self-determination when specifically designing research for Aboriginal & Torres Strait Islander. Austin Health reserves the right to withhold approval if the principles of self-determination have not been demonstrated.
- (9) Investigator initiated clinical research studies should use the following protocol templates:
 - a. For interventional clinical research – [SPIRIT Protocol](#)
 - b. For non-interventional and/or audits – Austin Health Non-interventional protocol template. This template is suitable for multi-site research
- (10) Austin Health can choose to accept other protocol templates if the information is considered complete and comprehensive. The Office for Research should be contacted prior to submission should you wish to use another protocol template.
- (11) For commercially sponsored clinical research studies, Austin Health will accept their protocol template, if it complies with the minimum standards outlined in the SPIRIT Protocol. Commercial sponsors are expected to make every effort to design and/or add Australian specific appendices to their protocol, to ensure their research projects meet clauses outlined in Part D of this policy.

Part E – Training and credentialing

Austin Health, through the Office for Research, will:

- (12) Provide ongoing training and education that promotes and supports responsible research conduct for all researchers and those in other relevant roles.
- (13) Provide access to TransCelerate R2 (E6) accredited Good Clinical Practice (GCP) training to all Austin Health staff and students involved in clinical research. Staff and students not affiliated with Austin Health at their own cost, access GCP training that meets this requirement.
- (14) In consultation with relevant universities and Medical Research Institutes, ensure supervisors of research trainees have the appropriate skills, qualifications and resources.

Sponsors of clinical research must:

- (15) Ensure all researchers involved in the conduct of clinical research have appropriate skills qualifications, experience and resources (including budget to cover the cost of the clinical research study); and
- (16) Ensure all researchers involved in the conduct of clinical research have current GCP training and other applicable training as appropriate for each clinical research study/protocol/project.

Part F – Feasibility Assessment

- (17) A feasibility assessment determines the practicality of the proposed clinical research study at Austin Health. Feasibility helps to determine whether a new clinical research study is relevant to Austin Health's patient population, has scientific/clinical merit, is viable to conduct at Austin Health and can be recruited for. It also assesses the resources required to conduct the clinical research study, identify risks and implement risk mitigation strategies.
- (18) A feasibility assessment must be undertaken for all research which uses Austin Health staff, patients, data and/or resources. This also includes services provided by third-party vendors for Austin Health. The extent of the feasibility assessment will vary from project to project. All projects must follow reasonable feasibility assessment, processes and documentation as outlined by the Office for Research. Feasibility assessment must consider the following:

- a. the Sponsor and sponsor requirements of Austin Health to conduct the study
 - b. Research is being designed and conducted by suitable qualified people
 - c. There the quality of the protocol, including scientific merit, use of consumers, and ethical considerations
 - d. Risk profile to the participant, research team and Austin Health
 - e. Possible benefits to Austin Health community, including culturally and linguistically diverse communities (CALD)
 - f. Agreement of supporting departments, collaborating organisations (including third-party vendors) and appropriate site-specific assessment conducted on a per project basis
 - g. SWOT analysis of the site, include recruitment, consent, appropriate management of work health and safety responsibilities for workforce
 - h. Proposed contractual and legal arrangements
 - i. Insurance and indemnity responsibilities
 - j. Ethical and regulatory requirements
 - k. Financial requirements
 - l. Sourcing of any interpreting services, space, materials or equipment to be used in the clinical research study
 - m. Proposed locations of clinical research study
 - n. Required capacity, training and competency of staff and student involved in and/or supporting the clinical research study
 - o. Research Data Management; and
 - p. Risk assessment and mitigation strategies to assure safety to participants, researchers and the organisation/s undertaking the research.
- (19) Where appropriate, researchers and sponsors wishing to access Austin Health Research Committees (including Ethics Committees) and/or using Austin Health as a site, should seek advice from Austin Health Office for Research as early as possible in the development and/or feasibility assessment.
- (20) Additional consultation regarding the roles and responsibilities may be required between researchers, sponsors, other organisations. The Office for Research will help to facilitate any consultation as required.
- (21) Where Austin Health considers taking the roles and obligations of the Sponsor, each situation will be assessed on its individual merits in consultation with the Office for Research.
- (22) If Austin Health is acting as the Sponsor and is collaborating with a Foreign Organisation to conduct a clinical research study in another country, any collaboration will be subject to due diligence and outlined in a contractual agreement. This agreement must be signed prior to site activation in the Foreign Country.

Part G – Equipment and materials

- (23) Researchers must source all equipment and materials through safe and ethical channels. The source of equipment and materials must be declared to the Office for Research.
- (24) Where appropriate, the Principal Investigator must ensure all contracts and warranties are in place before they use any equipment or materials for research purposes. Contracts and warranties should follow the same process as for other medical equipment and materials procured at Austin Health.
- (25) All staff and students should be adequately trained and/or certified to use any research equipment and materials. Training must be recorded in any competency system as directed by the Office for Research.

Part H – Insurance and indemnity

- (26) The Sponsor is responsible for arranging relevant insurance for clinical trials
- (27) The site/s approved to conduct the clinical research study is responsible for providing relevant indemnities. This includes third party vendor providers.
- (28) Evidence of insurance and indemnity must be provided upfront and is part of the due diligence process.
- (29) Insurance and Indemnity must be valid for the lifetime of the research project.

Part I – Intellectual property, commercialisation and research data management

- (30) Researchers must be aware of their responsibilities and obligations associated with intellectual property (IP), including ownership, copyright and patents, as outlined in any legal agreements and research data management plans. Any IP should be informed by the Austin Health Intellectual Property Policy, which is designed to ensure commercially valuable intellectual property is protected to the benefit of relevant parties and society.
- (31) Research data should be managed in accordance with the Austin Health research data management plan, which is approved as part of the lead Human Research Ethics Committee approval. Where possible, data management should comply with the Austin Health Research Data Management Policy.
- (32) It is the responsibility of the researcher to ensure the secure management, storage, retention and disposal of research materials, investigational products, devices and data throughout and after the completion of a research project for the mandated retention period. Researchers must comply with Austin Health Research Data Management Policy and Information Security Policy.
- (33) All research involving the use of personal information, particularly health information, must abide by the requirements outlined in the Australian Privacy Principles and relevant state and territory based Health Privacy Laws; the Guardianship and Administration Act 2019; the Health Records Act 2001; the [NHMRC Australian Code for Responsible Conduct of Research](#); [NHMRC National Statement on Ethical Conduct of Research in Human Research](#), and the legislation and regulations of the state or country where the research will take place.

Part J – Legal and contract administration

- (34) All research requires a written agreement between Austin Health, the Sponsor, and as appropriate, third-party vendors, other sites, Collaborative Groups, Medical Research Institutes and Universities. The Office for Research manages all research related agreements.
- (35) The type of research activity and nature of the relationship between collaborating parties will determine the most appropriate contractual agreement. Because the nature of these agreements can vary greatly, researchers should discuss their projects with the Office for Research for advice and to ensure that the correct documentation is used. Legal review of Research Agreements may be required for any agreement. Researchers cannot sign legal agreements or research contracts. These can only be signed by an authorised signing authority as listed for research agreements in the Austin Health [Delegations of Authority \(DoA\) Policy](#).
- (36) Research agreements are required even if there is no funding provided for the research.
- (37) The research agreement framework depends on multiple factors. These factors should be disclosed at time of feasibility to ensure that the Office for Research legal counsel can advise on the most appropriate research agreement/s.
- (38) Where an existing approved Partnership Agreement exists, this agreement shall be used if deemed appropriate for clinical research study in question.
- (39) All research agreements must be discussed with the Office for Research prior to execution and should follow the relevant process as outlined by the Office for Research.
- (40) Research agreements can only be signed by an authorised signing authority per the Delegations manual. Delegations will be managed in the same manner for other agreements. This means that sign-off from Principal Investigator, Finance Business Partner, Divisional Manager, Divisional Director, Legal Counsel and relevant Executive is required. This process is managed by the Office for Research.

Part K - Finances

- (41) Each research project must itemise all income and expenses for the life the project. The budget must be an accurate reflection of the true cost of the project, taking into account any funding shortfalls and outlining steps to seek additional funding to cover the full costs.
- (42) Researchers must ensure they have adequate funding to cover costs associated with their clinical research study. Financial accountability and transparency are the responsibility of the Principal Investigator.

- (43) Multiple funding sources may be required to adequately fund the clinical research study.
- (44) Austin Health supporting department costings are at the discretion of the supporting department. Supporting department costs and allocation of standard versus addition to standard of care. are to be outlined in a transparent and collaborative manner.
- (45) Under no circumstances can researchers and supporting departments charge Medicare and the sponsor for the same study procedure. If this occurs, relevant parties will be referred for investigation under the Austin Health Research Misconduct Policy.
- (46) Commercial Sponsors are required to pay for all study procedures outlined in their protocol. Commercial Sponsors cannot pressure Austin Health to accept a budget which does not cover our costs for the clinical research project. Matters pertaining to budget negotiations which cannot be resolved by the research team should be referred to the Office for Research.
- (47) All budgets must have a profit and loss summary. This needs to be reviewed and signed-off by the relevant department Finance Business Partner and r Head of Department, as part of the logistics and feasibility process managed by the Office for Research. Each supporting department must also complete their own profit/loss analysis with their respective finance business partner and head of department.
- (48) All budgets must include an overhead fee and addition of Australian Goods and Services Tax.

Part L – Risk management, mitigation and regulatory oversight

- (49) Research should be conducted in accordance with NHMRC Code of Conduct for research, ethical principles that have their origin in the Declaration of Helsinki and where appropriate, are consistent with Good Clinical Practice and applicable regulatory requirements. All research should be conducted in ways that ensure the rights, safety and well-being of participants. International research should also be conducted in accordance with any international legislation and standards.
- (50) Research must not be funded from unethical sources, the tobacco industry, related activities from tobacco companies or related organisations.
- (51) Research must be designed to generate reliable results.
- (52) Research must not commence without relevant approvals or acknowledgements in place. The types of approvals and processes vary from project to project. The Office for Research does not provide provisional approvals.
- (53) Research projects should be designed to minimise risks to participants, researchers and Austin Health. Risk mitigation strategies should be outlined in the protocol and/or relevant standard operating procedures. Risks may be identified at any point of the project and should be appropriately declared and managed.
- (54) Appropriate consent frameworks should be designed in line with best practice. Informed consent must be voluntary and based on a consent process that ensures participants (or their legally acceptable representatives, which applicable) are well-informed.
- (55) Research should be scientifically sound for their intended purpose, and where applicable should include considerations and methods for implementation of research to sustain continuous improvement in clinical care.
- (56) All staff and students must declare any real or perceived conflicts of interest in compliance with Austin Health's conflict of interest policy.
- (57) Any research involving the manufacture of therapeutic products used in clinical research must be manufactured in accordance with Good Manufacturing Practice principles and procedures to ensure therapeutic goods meet minimum quality standards.
- (58) Any research project using ionizing radiation, whether it is standard of care or above standard of care must seek Medical Physicist Report from Austin Health Medical Physicist. The process is outlined in the [Austin Health Radiation Safety Policy](#).
- (59) The Sponsor (for Commercially sponsored trials) and Principal Investigator (for investigator-initiated trials) are responsible for registering clinical trials in either the World Health Organisation (WHO) Registry Network or the Australian New Zealand Clinical Trials Registry. Researchers/sponsors can also choose to add to additional registries such as ClinicalTrials.gov and European Union Drug Regulating Authorities Clinical Trials Database.
- (60) Prior to commencing research, research projects using unapproved, experimental, or off-label drugs and medical devices, must complete a Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) registration with the Therapeutics Goods Administration.

- (61) Researchers must comply with Autonomous Sanctions and United Nations Security Council (UNSC) sanctions regimes.

Part M – Ethics and site-specific approvals

- (62) All clinical research studies must have relevant ethics, regulatory and site-specific approvals in place prior to starting the project.
- (63) Austin Health accepts Human Research Ethics (HRECs) approval from other National Mutual Acceptance approved HRECs. The lead HREC is the allocated HREC which provides ethical approval for the project.
- (64) For research projects approved by another HREC, researchers cannot commence the project at Austin Health until site-specific approval is granted.
- (65) Management of post-approval requirements such as amendments to approved projects, safety reporting, annual and final reports are in accordance with sponsorship type and lead HREC requirements. These are outlined on the Office for Research website.
- (66) Researchers using Austin Health BioResources Facility must seek ethics approval from Austin Health Animal Ethics Committee (AEC). Researchers must be employed by one of our research partners who hold a current Scientific Procedures Licence (SPPL) issued by Animal Welfare Victoria.
- (67) Researchers using Genetically Modified Organisms must seek Institutional Biosafety Committee (IBC) approval from Austin Health IBC. Contact Office for Research if your clinical trial requires IBC approval, and you have received approval from another IBC.

Part N – Monitoring and auditing

- (68) Safety of research participants, staff and students should be prioritised over all other aspects of the research. Researchers must comply with safety reporting requirements as outlined on the website. The Office for Research should be notified immediately if they become aware of the following:
- reportable event that occurred at Austin Health per [Incident Management Procedure](#) and [NHMRC Safety Reporting Guidelines](#)
 - information that changes the risk assessment and mitigation strategies
 - potential or known breach of any law, regulation, external guideline of code applicable to the conduct of research; and
 - matters pertaining to the ethical acceptability, safety or integrity of the research, research staff and participants.
- (69) Austin Health and sponsors have an obligation to monitor the progress, integrity and compliance of research projects in compliance with this policy. Austin Health will review any existing or emerging risks for researchers, or the organisation as part of its Governance responsibilities. The Office for Research in consultation with Quality and Safety are responsible for designing, implementing, conducting and reporting on Austin Health's audit and monitoring program.
- (70) Monitoring programs will be conducted in line with NHMRC Responsible Code of Conduct for Research, The Commission on Health Quality and Safety Accreditation requirements and relevant ethical and/or legislative guidelines. Mechanisms for monitoring may include the following:
- Reports from researchers
 - Reports from independent agencies (such as monitoring reports, audit report, data and safety monitoring boards)
 - Regular or spontaneous inspection of research sites, and documentation; and
 - Interviews with researchers, participants, and other forms of feedback.
- (71) The frequency and type of monitoring will be conducted under the risk-based monitoring framework. The Office for Research must ensure systems are in place for the management of complaints, including research misconduct and fraud. All roles and responsibilities of the Austin Health corporate and clinical governance workforce have obligations to be aware of integrity requirements and to report potential breaches and/or issues to the Office for Research.

Part O – Complaints handling

- (72) Complaints about the conduct of research by Austin Health staff, students and/or the sponsor of the research should be made per the complaints process outlined on the website.
- (73) Allegations of research misconduct will be managed per Austin Health Research Misconduct Policy.

Part P – Reporting

- (74) Researchers, clinical units, and Austin Health must comply with reporting requirements as outlined by the Commission on Quality Health and Safety (known as the National Aggregate Statistics), the Victorian Department of Health, and reporting as outlined in relevant approval letters. Reporting requirements for annual, final, safety events, amendments to approved projects and risk-based monitoring are outlined on the website.

Part Q – Study completion & archiving

- (75) A research project is considered complete when there are no active participants and no participants in follow up.
- (76) Research projects may be terminated or abandoned earlier than planned due various reasons. Project terminations or abandonment must be reported to the Office for Research via a Progress Report.
- (77) Progress Reports must detail the project progression until end of project activities including date of project closure, recruitment, withdrawal of participants and lessons learned.
- (78) Completed projects are to be archived by the department in charge in accordance with Austin Health Corporate Records Management policy and research project archival duration requirements.

Part R - Research partner principles – research funds

- (79) In cases where Clinical Trials and other research where Austin Health is directly approached from the Commercial Sponsor or Contract Research Organisation (CRO), Austin Health will be the administering body. Research Partner resources are needed, this will be managed on a case-by-case basis via a Service Level Agreement between Austin Health and the Research Partner.
- (80) If the Research Partner has directly applied for grants and been awarded a grant (competitive or not), or has received money from the Commercial Sponsors, or other co-operative groups, the Research Partner will become the administering body and therefore the Sponsor of the trial.
- (81) Each party will articulate who is responsible for what costs in the relevant research agreement/s.
- (82) For research administered by a Research Partner, Austin Health staff wishing to apply for funding via these pipelines must hold a joint appointment with the Research Partner and must apply via Research Partner processes.

Part S - Research partner principles – research involving Austin Health patients, staff, data and biospecimens

- (83) **Definition of a Site:** Austin Health is a “site” when research meets one or more of the definitions below:
 - Directly or indirectly impacts on Austin Health patients (either in or outpatients)
 - Uses Austin Health data and/or biospecimens
 - Uses Austin Health resources
 - Could impact on Austin Health’s reputation; or
 -

- Requests our Research Partners to act as local Sponsor, where the project uses Austin health patients, data, resources and/or impacts Austin Health's relationship with the Research Partner.

(84) The Research Partner commits to compliance with this policy, and its relevant policies and procedures for all research it conducts where Austin Health is a "site".

Investigator Initiated Research where Research Partner will act as Sponsor/Local Sponsor

(85) Interventional Research

- The Research Partner will act as Sponsor of any human research when they are the administering body of the funds or when they have been asked to act as local sponsor by a Third Party as outlined in a separate funding agreement (or equivalent).
- The Research Partner commits to complying with Austin Health's Conflict of Interest Policy and/or Austin Health Open Disclosure procedure by declaring all funding sources and other perceived or potential conflicts of interests that may impact on the ethical suitability of any research. This may include from time to time working with Austin Health to provide confidential information to resolve all Open Disclosure issues.
- When the Research Partner is acting as Sponsor, the Research Partner agrees to take on all Sponsor Responsibilities as defined in the relevant clinical trial research agreement (or equivalent).
- When acting as local sponsor the Research Partner agrees to provide Clinical Trials Insurance (or equivalent) for all projects.
- Austin Health Site Principal Investigator must hold a joint appointment with both Austin Health and the Research Partner. The manager of each area affected by the research activity must be approached to ensure operational costs and resources are appropriately recovered. This must be done during the study feasibility process, and prior to submission of the research project for ethics and/or site-specific authorisation review.
- The Research Partner agrees to follow all of Austin Health's relevant policies and procedures prior to submitting any research project for ethical review or Site-Specific Authorisation (SSA) at Austin Health.
- The Research Partner agrees to submit any single site projects using Austin Health patients/staff, with or without their data and/or biospecimens, to the Austin Health Human Research Ethics Committee (or sub-committee) in accordance with the current procedures outlined on the Office for Research website.
- The Research Partner agrees to submit any projects not relevant to the hospital, to its University partner Research Office.
- Both parties agree to notify one another of any incidents regarding alleged non-compliance or safety issues with an approved human research ethics project as defined below:
 - By Institute staff or joint Honorary appointments; and/or
 - Relating to Austin Health patients/staff with or without their data and/or biospecimens.

(86) Research where the Research Partner will act as a sub-contractor to Austin Health (including Commercially Sponsored Trials)

- To support research by Austin Health, the Research Partner agrees to provide fee-based services to Austin Health. For Commercially Sponsored projects, resourcing between the Research Partner and Austin Health will be outlined during the Feasibility process, and fees will be paid via a Service Level Agreement between Austin Health and the Research Partner. Both parties must agree to the fees prior to signing of any clinical trial research agreement (or equivalent).
- The Austin Health Site Principal Investigator must hold an Austin Health appointment and may hold a joint Austin Health and Research Partner appointment but cannot hold only a Research Partner appointment.

(87) Non-Interventional Research using patient data and/or biospecimens

- When the Research Partner wishes to use hospital patient data and/or biospecimens, approval from Austin Health Human Research Ethics Committee or equivalent is required, and the steps outlined in clauses 1.3.1 (Investigator Initiated Research when the Research Partner is acting as Sponsor/Local Sponsor).

Part T - Research involving the use of animals for scientific purposes

(88) **Animal Research Ethics Agreement**

- a. For work being conducted on Austin Health premises, the Research Partner agrees to submit proposals for approval to the Austin Health Animal Ethics Committee (AEC). This must be done under the Research Partner's own Scientific Premises Licence (SPPL) issued by Animal Welfare Victoria.
- b. For work conducted across multiple premises, ethical proposals pertaining to the body of work under the Animal Ethics Committee of each premises involved must be submitted to the Austin Health AEC for approval. Where there is a transfer of the animals across licensed premises.
- c. The Research Partner shall not act in a way that is contrary to any applicable legislation or guidelines including the National Health & Medical Research Council Australian Code for the care and use of animals for scientific purposes.

(89) **Austin Health will ensure that:**

- a. The Austin Health AEC will consider and where appropriate, approve, review and monitor all projects involving animals housed on its premises conducted by staff and students from the Research Partner.
- b. The Austin Health AEC and animal facilities will keep the Research Partner researchers informed promptly of any relevant information which is received and/or considered by the Austin Health AEC and animal facilities.
- c. It promptly notifies the Research Partner and any other related approving AEC of any incident it or its staff become aware of regarding alleged non-compliance with an approved AEC project if it involves the Research Partner staff or students.
- d. Austin Health Office for Research and/or AEC has the right to suspend or terminate a proposal approved by the Austin Health AEC or a related project approved by another AEC (including those under a delegation of responsibility) at any time for any reason, including, but not limited to actual or alleged non-compliance with an approved AEC project or any actual or alleged breach of the Australian Code of Conduct for Responsible Research.
- e. Austin Health agrees to provide appropriate training and support and services to the Research Partner staff and student.

(90) **The Research Partner will ensure that:**

- a. The Research Partner researchers (including staff and students) will comply with the reasonable and properly made directions or determinations of the Austin Health AEC (including suspending or ceasing any experiment or procedure which is not compliant or does not have appropriate approval by the AEC), the details of which will be made known prior in writing to the Research Partner, in accordance with our documented policies and procedures.
- b. Research projects involving animal work to be conducted on Austin Health licensed premises will be submitted for approval to Austin Health AEC.
- c. All necessary assistance is provided to Austin Health to provide information and work with Austin Health for matters pertaining to non-compliance, research misconduct and any audits.
- d. It promptly notifies Austin Health of any incident it becomes aware of regarding alleged non-compliance or research misconduct identified by the Research Partner staff or students relating to an Austin Health AEC approved project.

Part U - Institutional Biosafety Committee (IBC) for research involving genetically modified organisms

- (91) Pursuant to the Gene Technology Act 2000 (2018 edition) (Cth), and the Gene Technology Regulations 2001 (Cth) (**Gene Technology Legislation**), the Research Partner is an accredited Organisation which can apply for a license to deal with genetically modified organisms (GMOs). The Research Partner is required to meet its legislative requirements as well as meet the conditions of accreditation imposed by the Office of the Gene Technology Regulator (**the Regulator**) under the Gene Technology Legislation.
- a. For work being conducted on Austin Health premises, the Research Partner agrees to submit projects for approval to the Austin Health Institutional Biosafety Committee (IBC) and will follow relevant Austin Health policies and procedures.

- b. For work being conducted at another premises, the Research Partner agrees to submit to the relevant IBC for approval.
- c. For work conducted across multiple premises, proposals pertaining to the body of work under each IBC must be submitted to the IBC whose jurisdiction it is to provide approval.
- d. Austin Health is not an accredited IBC, this means we cannot provide IBC approval for clinical trials across Australia.

(92) **Austin Health will ensure that:**

- a. The Austin Health IBC performs the role of the IBC for our precinct Research Partners in accordance with the clauses above.
- b. The Austin Health IBC assesses projects to work with GMOs submitted to the Austin Health IBC in respect of work conducted using Austin Health premises, including leased wet labs.
- c. It promptly notifies Research Partners of any actual or anticipated cancellation, suspension or variation of Austin Health's status as an accredited Organisation under the Gene Technology Legislation.
- d. the Austin Health IBC is properly constituted at all times in accordance with Gene Technology Legislation and any applicable guidelines.
- e. It reports promptly to the representative nominated by ONJCRI, any significant issues relating to GMOs or an approved project.
- f. The Austin Health Office for Research and/or IBC has the right to suspend or terminate a proposal approved by the Austin Health IBC or a related project approved by another IBC (including those under a delegation of responsibility) at any time for any reason, including, but not limited to actual or alleged non-compliance with an approved IBC project or any actual or alleged breach of the Australian Code of Conduct for Responsible Research.
- g. It will provide appropriate training and support and services to Research Partner staff and student.

(93) **The Research Partner will ensure that:**

- a. It complies with the conditions of approval under Gene Technology Legislation and any Containment Facilities.
- b. Research staff and students will comply with Austin Health IBC approval and directions, including suspending or ceasing any work which is not compliant or does not have appropriate approval.
- c. It permits Austin Health to inspect Physical Containment Facilities as required by Legislation.
- d. All relevant personnel dealing with GMOs are fully informed and trained in the management of GMOs.
- e. It notifies Austin Health IBC of any actual or proposed changes in relation to dealings with GMOs, including information on risks associated with dealings, location of dealings or when the dealings are completed or abandoned.
- f. It notifies Austin Health IBC of any incidents involving a GMO, any laboratory acquired illness or any breach of containment relating to a project approved by Austin Health IBC.
- g. It maintains a register of current approved projects.
- h. It promptly notifies Austin Health of any incident it becomes aware of regarding alleged non-compliance or research misconduct with an approved IBC project by ONJCRI staff or students.

Part V - Research partner principles – research outputs and recognition

- (94) The following principles should be followed in accordance with this policy and the Austin Health Research Authorship and Outputs Policy:
- a. When the Research Partner is acting as Sponsor for the trial, and will be using resources from the Hospital, such as patients and/or patient data or biospecimens, then all public documents, and scientific outputs will be co-branded as “the Research Partner and Austin Health”.
 - b. When the Research Partner is acting as Sponsor and the Co-ordinating/Principal Investigator has a joint appointment with the Research Partner and Austin Health, the affiliation of the Co-ordinating/Principal Investigator should be spelled out in full in any public documents.

- c. Under the Australian Responsible Code of Conduct for Research, R26, when the Research Partner is acting as Sponsor or Local Sponsor and is using Austin Health for a single site study, it will acknowledge Austin Health under its acknowledgements. This also applies for basic laboratory outputs using Austin Health Bioresources Facility.
- d. When the Research Partner is acting as Sponsor for the trial, the research will be counted towards the Research Partner research portfolio.
- e. When Austin Health is acting as Sponsor for the trial, the research will be counted towards the Austin Health research portfolio.

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Author: Manager, Office for Research

Contributor(s): Director of Research

Legislation/references/supporting documents:

- [NHMRC Australian Code for the Responsible Conduct of Research \(2018\)](#)
- [NHMRC Authorship Guide](#)
- [NHMRC Publication and dissemination of research guide](#)
- [NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018](#)
- [AIATSIS Guidelines for Ethical Research in Australian Indigenous Studies 2012](#)

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