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Purpose

The purpose of this document is to set out the overarching requirements for conducting research at Barwon Health and to give guidance to both researchers and reviewers to ensure that the research being undertaken is safe, valid, high quality and fulfils all regulatory and institutional requirements. This Research Handbook forms part of the Research Governance Framework for Barwon Health.

Link to Policy

The Research Handbook is linked to the Research Policy.

Target Audience

This Handbook applies to all research undertaken at Barwon Health (i.e. involving Barwon Health staff, participants, and/or resources), or conducted by Barwon Health (i.e. where Barwon Health is the sponsor of a research project conducted at a site under the control of Barwon Health or at another location). It applies to all Barwon Health employees, non-employed staff and to all relevant external persons and parties engaged in research activity at Barwon Health.

Researchers intending to conduct research at Barwon Health should first read this Handbook and familiarise themselves with Barwon Health's:

- Research Policy

- Research Governance Framework
- Research Strategic Plan
- Research Procedures within Prompt

Where applicable, references are included throughout this document and supporting SOPs. A summary of key documents and source locations is provided in the References & Resources (Appendix 1) section of this Handbook.

Definitions

Term	Definition
The Code	Means the Australian Code for the Responsible Conduct of Research 2018
Animal Code	The Australian code for the care and use of animals for scientific purposes 8th Edition 2013 (updated 2021)
ARPANSA Code	The Code of Practice – Exposure of Humans to Ionizing Radiation for Research Purposes Radiation Protection Series Publication No. 8
Certification	Certification by the Regulator of a facility to a particular containment level under the Act
Clinical Trial	As defined by the World Health Organisation, a clinical trial is: *Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.*
Data Breach	Where any data held by Barwon Health are accessed, or disclosed, without authorisation, or are lost.
Dealing	As defined by the GT Act to deal with in relation to a GMO, means the following: (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; (h) transport the GMO; (i) dispose of the GMO; and includes the possession, supply or use of the GMO
External research contractor	Is a person who wishes to conduct research at Barwon Health (either as an investigator or supporting role) without having an affiliation or appointment at Barwon Health This may include but is not limited to: academic; external institution researchers or research support staff; volunteer/work experience.
External research student	Is a person who intends to conduct a higher degree research project without having an affiliation or appointment at Barwon Health.
GCP	Good Clinical Practice *Is defined as an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of humans. The term "GCP" within this*

	document is with reference to two internationally accepted standards: (1) ICH GCP and (2) ISO 14155
GMO	Genetically Modified Organism As defined by the Gene Technology Act 2000 is: *(a) an organism that has been modified by gene technology; or* *b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or* *I anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;*
Investigator	An investigator is defined as a member of the research team who has the qualifications, training and delegated authority to conduct integral study procedures. This may include but is not limited to: Provision of an intervention; Interpretation of results/outcomes; Decision making authority with regards to treatment/intervention; Conduct of Interviews/focus groups; Protocol design and development.
IoD	Instrument of Delegation
ISO	An independent non-governmental international organisation for standardisation with worldwide membership of national standards bodies including Australia.
ISO 14155:2020	An internationally recognised standard that addresses Good Clinical Practice (GCP) for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical devices.
ISO/IEC 27001	An internationally recognised Information Security Management System (ISMS) standard. It is a framework for the requirements to manage an organisation's information security risks.
ISO 9001:2015	An internationally recognised standard, which sets out the fundamental concepts and principles of quality management
National Statement	Means the *National Statement* on Ethical Conduct in Human Research (2007) updated 2018
Negligible Risk Research	Is defined as research in which the only foreseeable risk is no more than inconvenience.
NMA	National Mutual Acceptance Is defined as the system of single scientific and ethical review of multi-centre human research projects conducted in public health organisations.
NLRD	Notifiable Low Risk Dealing is an activity with a GMO that is - undertaken in containment in a facility certified by the Gene Technology Regulatory or approved in writing by the Regulator

	- assessed as posing low risk to the health and safety of people provided certain risk management conditions are met
Non-identifiable data	As adopted by the NHMRC: *Data which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown.*
PI	Principal Investigator – Is the person responsible, individually or as a leader of the research team at a site, for the conduct of a clinical trial at that site. As such, the Principal Investigator is responsible for adequately supervising his or her research team.
Research	Means human research which is research conducted with or about people, or their data or tissue as described in the current version of the *National Statement* and *the Code*.
Research Governance	Refers to the processes used by an organisation to ensure that it is accountable for the health and medical research conducted under its auspices.
Research Governance Framework	Outlines the structure and roles and responsibilities for managing research in an organisation. A robust RGF is comprised of research policies, procedures, training and a quality assurance program.
Site	Is a facility, location or service where the research is being conducted.
Site Authorisation	Means the authorisation granted by the Chief Executive or delegate of Barwon Health for the commencement of a research project at that site.
Sponsor	As defined by GCP "Sponsor" is *an individual, company, institution, or organisation, which takes responsibility for the initiation, management and financing (or arranging the financing) of a Clinical Trial.* The Sponsor carries the medico-legal responsibility associated with the conduct of a Clinical Trial. The use of the term "Sponsor" within this document is synonymous with the term "Trial Sponsor".
The GT Act	The Gene Technology Act 2000

Background

Barwon Health conducts clinical and health services research that is safe, appropriate and aligned with the Barwon Health Research Policy, Barwon Health Research Strategic Plan, the National Statement on Ethical Conduct in Human Research, the Australian Code for Responsible Conduct of Research, the National Clinical Trial Governance Framework, and Therapeutic Goods Administration's Guideline for Good Clinical Practice.

All research at Barwon Health is conducted to the highest ethical standards and protects the welfare, rights, safety and dignity of participants in accordance with Australian and Victorian regulatory and legislative requirements.

This procedure manual forms part of the Barwon Health Research Governance Framework that ensures Barwon Health has effective research governance procedures that enable the delivery of safe and high impact research in accordance with the National Clinical Trials Governance Framework that is integrated into existing clinical and corporate governance structures. It is expected that researchers follow the Australian Code for the Responsible Conduct of Research 2018 (*the Code*) which articulates the broad principles that characterise an honest, ethical, and conscientious research culture. *The Code* and supporting best practice guides outline the expectations for the conduct of research in Australia or research conducted under the auspices of Australian institutions. It establishes a framework for responsible research conduct that provides a foundation for high-quality research, credibility, and community trust in the research endeavour.

Research Governance

Broadly, the term “Research Governance” means a set of relationships and responsibilities established by a health service organisation between its state department of health, governing body, executive, clinicians, patients, consumers and other stakeholders to ensure good clinical outcomes. It ensures that the community and health service organisations can be confident that systems are in place to deliver safe and high-quality health care, and continuously improve services[1].

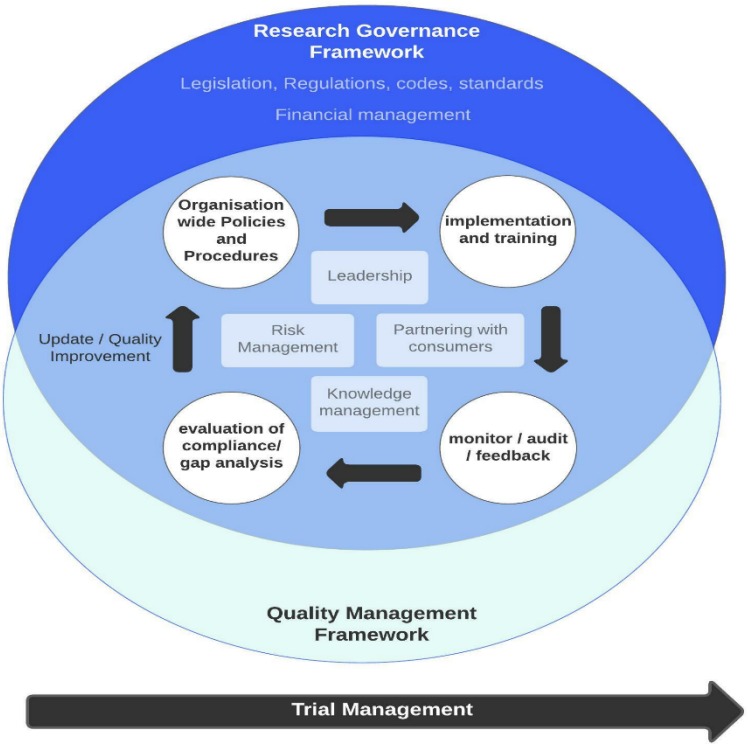
Research governance applies to all forms of human research and addresses the protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory compliance, risk management and monitoring arrangements specific to Barwon Health, whilst promoting and fostering a research culture of high integrity and good practice. At an organisational level, Research Governance provides assurance that studies have been designed to be feasible, financially sustainable, and delivered in a manner that is synchronised with participant’s routine clinical care and staff routine work.

Barwon Health has implemented a Research Governance Framework (RGF) which ensures research conducted at, or by, Barwon Health meets the highest ethical, scientific, regulatory and professional standards. Key components of the Barwon Health RGF include policies and procedures, risk management, leadership, training and a quality assurance to help guide responsible conduct of research (see Figure 1).

All research projects conducted at Barwon Health or sponsored by Barwon Health must meet appropriate governance standards, and be authorised by the Chief Medical Officer (CMO) or delegate before commencement (as described in the Barwon Health Research Governance SOP and Barwon Health Instrument of Delegation (IoD). The governance processes ensure that ethical, legal, regulatory, strategic, and logistical requirements are met in a way that is proportionate to the potential benefits and harms of the research, that all parties are aware of their responsibilities and that the relevant approvals are in place.

Research Governance at Barwon Health is overseen by the Research Development Unit (RDU). Further information regarding Barwon Health’s Research Governance Framework and its supporting policies and procedures can be found on the Research Directorate Web Page and on Prompt.
Figure 1. An organisation's Research Governance Framework (RGF).

[1] Australian Commission on Safety and Quality in Health Care, The National Clinical Trials Governance Framework and User Guide, 2022. Availabe at: https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide



Compliance with NCTGF by design

HANDBOOK

The table below provides quick links for navigating the Research Handbook.

Barwon Health Research Governance Considerations
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Researcher Requirements

Training Requirements

Good Clinical Practice

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of humans, and ensures the roles and responsibilities of the Institution, HREC, Investigators and Sponsor.

Compliance with GCP is incorporated by reference in the Therapeutic Goods Regulations (1990) and is a requirement for the conduct of clinical trials involving unapproved therapeutic goods at Barwon Health.

The TGA recognises two internationally accepted GCP guidelines:

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP) with TGA annotations (For investigational medicinal products and investigational biologicals)
- Clinical investigation of medical devices for human subjects – Good clinical practice (ISO 14155) (For investigational medical devices)

All researchers conducting **clinical trials** are required to provide evidence of GCP training within the last 3 years (also a requirement of Researcher Credentialing). This includes Associate Investigators, Clinical Trial Managers/Coordinators and Research Assistants.

GCP training is also required for Principal Investigators on all **Clinical Research** Projects, and is highly recommended for all other researchers as it provides useful information related to data integrity and patient safety that can be applied across all areas of research.

GCP training must be updated every 3 years and delivered by a TransCelerate recognised GCP provider (a list of providers can be found on the TransCelerate website).

TransCelerate recognised A-CTEC GCP training is available to Barwon Health Staff via the GROW learning management system. Researchers are required to attach their GCP certificates within GROW. Completion of GCP training via GROW is mandatory for all **new** clinical researchers, including Principal Investigators, Associate Investigators, CT Managers, CT/Research Coordinators, Research Assistants, HREC members and Research Development Unit staff. The RDU may also ask existing researchers to complete A-CTEC GCP training via GROW as risk management following audits. If GCP training does not appear as mandatory training within your GROW account, please ask your manager to add you to the researcher list in GROW.

However, it is important to note it is the individual's responsibility to ensure they are conversant with any changes that occur between the 3 year intervals to GCP, as well as changes to laws, regulations, guidelines and directions applicable to their work.

Researcher Credentialing

Any researcher engaged in health and medical research involving Barwon Health's participants, staff and/or resources must be authorised to conduct research at Barwon Health.

Researcher Credentialing is a process that ensures all individuals (including Barwon Health staff, external research contractors, volunteers and external research students) conducting human research at or for Barwon Health are adequately qualified and experienced or supervised (where applicable) and authorised to safely undertake the relevant research related activities.

Further information regarding the researcher credentialing process at Barwon Health is outlined in the Barwon Health Researcher Credentialing SOP.

Principal Investigator Requirements

All research being conducted at Barwon Health must have a site Principal Investigator (PI) responsible for the safe and ethical conduct of the research project at Barwon Health who is a credentialed researcher and has appropriate clinical scope of practice.

A senior researcher/supervisor with employee status or equivalent joint or honorary researcher credentialed appointment at Barwon Health recognised by BH People and Culture, must be nominated as the PI to ensure there is a line of accountability. The PI may delegate research activities as listed on the delegation log, however they still retain overall responsibility and must ensure delegates only conduct trial activities within their scope of practice. All IMP trials must have a medical clinician assessing capacity to consent, inclusion/exclusion criteria and conducting the process of consent.

The only exception to the requirement for a BH PI, is where BH Staff, who are conducting research as a student for a higher degree, must list their University supervisor as Principal Investigator. This is because student researchers undertaking a PhD or Masters Project cannot be the PI at Barwon Health, unless approved by the Barwon Health CMO in advance. As per all research projects being conducted at Barwon Health, a Barwon Health HoD must sign off on the project. University Department Head signoff is not accepted.

The application of a particular investigator category (i.e. PI or Sub-Investigator) for the purpose of research ethics and governance consideration does not influence or reflect the authorship nomenclature or ownership of the protocol, it is simply an indication of who is ultimately responsible for the conduct of the research at Barwon Health.

New Research Proposals

Barwon Health has an overarching Research Strategic Plan that all researchers should be familiar with when planning to undertake research at Barwon Health. It is important that all researchers ensure that their proposed research is aligned with the Barwon Health Research Strategy and can be accommodated. To achieve this Barwon Health requires all PIs to discuss their projects with the relevant people that will be involved in any way at Barwon Health. In practice, this means that PIs should speak with all Heads of Department that are involved in their project i.e. Medical Records, Radiation Safety, Pathology, Pharmacy etc. and any staff who may need to be involved, as well as senior managers and/or executives where there are significant impacts on resources or potential risks involved.

Researchers are expected to identify, assess and mitigate risks associated with all new research activities. The RDU is available to assist you with this process and development of a Risk Management Plan if required. We strongly encourage early conversations with all stakeholders about the risks and resource requirements, as experience dictates that failure to do so can result in delays or failure of the study at critical time points.

It is prudent to discuss projects with the RDU at the time of site selection or at the concept or project design stage for Investigator Initiated Trials (IIT). This allows the RDU to ensure all relevant

stakeholders have been included, and assist researchers to avoid problems that may otherwise arise. At this point, the RDU may advise your project proposal be presented to the Research Management Committee (RMC) as well as the New Technology and Clinical Practice Committee (NTCP).

The RDU offers researchers assistance with new submissions, including support for study start-up, feasibility assessment, sponsorship approval, ethics submissions, budgeting and contracting.

The RDU has developed a process of endorsement for Investigator Initiated studies whereby researchers can engage with senior, experienced researchers and biostatisticians for guidance and support in developing a research question as well as protocol design and development.

Where researchers require access to inpatient or outpatient clinical space in which to conduct their trial or study, RDU can assist with evaluating available space for suitability. Space is limited so it is important to engage with RDU as early as possible.

For researchers new to industry sponsored or investigator initiated studies, RDU can provide guidance directly to researchers or link the researcher with other experienced trial investigators.

Depending on the activity and type of study, RDU may be required to charge for some of the above services. For more information contact RDU on RDU@barwonhealth.org.au

Protocol Design

A high-quality and well thought out protocol will assist in smooth project implementation, participant safety, the generation of quality and appropriate data, a reduction in avoidable amendments and deviations as well as facilitating efficient appraisal of the study's scientific and ethical considerations.

The team involved in protocol development should include, but is not limited to: Health professionals with subject matter expertise (e.g. therapeutic area, investigational agent or class of agent), statisticians, experts with clinical research regulatory and operations (coordination, quality assurance and data management) experience and individuals or groups who can provide insight into the lived experience, values and priorities of consumers and communities.

Consumer and community engagement should also be sought wherever possible throughout all stages of health and medical related research (from planning through to conduct of research and evaluation of outcomes) thereby ensuring the research is relevant to community needs and increased opportunities to continuously improve the quality of research (see NHMRC Consumer and Community Engagement and National Clinical Trials Governance Framework and User Guide).

Resources, such as the Australian Clinical Trials Alliance (ACTA) Consumer Involvement and Engagement Toolkit (2022), provide practical advice on how to engage consumers in clinical research protocol development and delivery. Researchers are also advised to visit the RDU Consumer Involvement in Research webpage for further practical advice.

Use of an appropriate protocol template is essential to ensure that all risk factors and study design requirements have been considered when planning a research project. For Clinical Trials, the protocol should be based on the recommendations from the SPIRIT Statement. Although the SPIRIT statement is designed for clinical trials the relevant principles can also be applied to non-interventional or health and social science research. Where appropriate, it is recommended that researchers follow the James Lind Alliance and COMET methodology.

Barwon Health RDU Protocol Template can be accessed within the RDU website library of forms.

For support with protocol development please contact your Department Research Lead OR RDU@barwonhealth.org.au

Ethical Review of Human Participant Research

Institutions that conduct research involving humans are required to ensure that any research projects protect the rights and safety of participants, that is, it is 'ethical'. The National Statement on Ethical Conduct in Human Research 2007 (updated 2018)(*National Statement*), AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (AIATSIS code), 2020, Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders, 2018 and Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2017 (the ART Guidelines) provide a series of guidelines to promote and inform the ethical conduct of human research. Human research may also be subject to other legislative acts, such as the Federal Privacy Act (1988, 2001) and the Therapeutic Goods Act (1989), as well as state and territory legislation. In these instances, the research is also governed by federal and state legislation. [RL1] Further information on the regulatory requirements for specific areas of research are provided in subsequent sections of this handbook and should be referred to where relevant.

While it is important to ensure all activities are ethically sound, not all projects require review by a Human Research Ethics Committee (HREC). The level of review will be commensurate with the level of risk to which participants are exposed.

Risks include physical, emotional, psychological, social, legal and reputational risks to participants, their families and communities, researchers, and/or institutions involved in the research. The following sections provide further guidance on the applicable HREC and non-HREC review pathways for research projects at Barwon Health.

Research Requiring HREC Review

- The *National Statement* describes a variety of ways in which ethical review of research involving humans may be conducted. For research involving more than low risk (i.e. more than discomfort) and/or involving overlap with legislation, review by a formally constituted HREC is generally required. Barwon Health fulfils its obligations for ethical review in the following ways;
- For **negligible risk research** as defined by the *National Statement* non-HREC approval pathways are permissible (see below). In practice this means that the RDU will organise an appropriate level of review and can produce letters that outline approval that will satisfy funding bodies and journals where necessary.
- For **low risk studies** as defined by the *National Statement*, approval may be granted either by an HREC or low-risk subcommittee. In practice, the majority of these studies will still need to go through an HREC and most have expedited pathways for such reviews. The RDU recognises the ethical approval of NHMRC certified ethics committee under NMA (National Mutual Acceptance) and may accept other HRECs review, by prior agreement from the RDU.
- For studies, deemed **greater than low risk** as defined by the *National Statement,* and in particular studies that require notification or review by the TGA (i.e. CTN/CTA) Barwon Health requires ethics review by a HREC that has demonstrated capacity to review these. In practice this will most likely be through a certified HREC. In addition, studies that involve the use of a waiver of the requirement for consent must be reviewed by a HREC even if they are deemed to be low or negligible risk. Barwon Health requires that the ethics review is provided by a NHMRC certified reviewing HREC.

The Coordinating Principal Investigator (CPI) is the individual who takes overall responsibility for the research project and submits the project for ethical and scientific review. The CPI is responsible for ongoing communication with the HREC and passing on any outcomes from this to the PI's at each site where the research is conducted. Where the research is conducted at Barwon Health only (i.e. single centre research), the CPI and Barwon Health PI are synonymous.

Non-HREC Review Pathways

According to *the National Statement*, institutions may employ non-HREC mechanisms for review for research that is low risk or of negligible risk (s5.1.18-5.12.21). The RDU currently reviews low risk research via BH HREC. Negligible Risk research is reviewed within 7 days by the RDU team. Submissions are accepted via Ethical Review Manager (ERM) on the QA form, and submissions meeting negligible risk requirements will receive an approval/exemption letter via ERM that may be used for the purposes of publication.

Conduct of Clinical Trials

The conduct of clinical trials in Australia is regulated by the Therapeutic Goods legislation. The legislation, stipulates that a product may not be manufactured, imported, exported or supplied in Australia unless it is either entered onto the Australian Register of Therapeutic Goods (ARTG), or is "exempt" from the requirement for such entry.

The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods. The TGA is responsible for regulating the use of therapeutic goods supplied in clinical trials in Australia under the therapeutic goods legislation. The TGA provides a series of guidance on its requirements, with the main resource relevant to most clinical research in Australia being the Clinical Trials Handbook.

The Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) schemes are the two such pathways managed by TGA avenues of "exemption" that allow unapproved therapeutic goods to be supplied to members of the Australian public.

All Clinical Trials involving unapproved therapeutic goods conducted under the CTN/CTA scheme must have an Australian Sponsor. Clinical Trial Sponsors may be commercial entities such as pharmaceutical companies, biotech companies, Clinical Research Organisations (CROs), collaborative groups or Investigator's or their employers.

The Sponsor is responsible for the initiation, management and financing (or arranging the financing) of the trial and carries the medico-legal responsibility associated with its conduct. The Sponsor is also the entity that is responsible for submitting a CTN/CTA and any updates or reports (such as safety reporting) required to be submitted to the TGA during the conduct of the research project.

The CTN/CTA for a Clinical Trial to be conducted hosted at Barwon Health must be submitted to the RDU and acknowledged by the TGA prior to commencement at Barwon Health.

Barwon Health as Clinical Trial Sponsor

The sponsor of a research project is the company, institution or organisation, body or individual that takes overall responsibility for the conduct of the research and usually initiates, organises and supports the research.

Barwon Health may act as a Sponsor for a clinical trial initiated by Barwon Health staff. However, approval to act as a Sponsor is not automatic. The Coordinating Principal Investigator (CPI) (where a multi-site trial), or Principal Investigator (PI) (where the trial is single site) should discuss the intention for Barwon Health to be the Sponsor with the Barwon Health RDU as early as possible and prior to the HREC submission.

The CPI/PI must submit a sponsorship request through the RDU. Barwon Health Sponsorship must be confirmed by the Research Advisory Committee prior to the HREC submission OR site governance submission (where a multisite project requires each site to act as their own sponsor).

Where Barwon Health is the sponsor of a clinical trial CTN/CTA trial, Barwon Health it must satisfy itself that the study meets the relevant regulatory requirements standards and ensure that arrangements are put and kept in place for management, monitoring and reporting (see TGA Clinical Trials Handbook, ICH GCP Section 5 and ISO 14155).

The RDU acts as TGA Administrator for Barwon Health and can provide PI access to the TGA online CTN submission system. The RDU can guide you through your CTN submission. The RDU will review and submit final CTNs to the TGA for Barwon Health sponsored trials. Payment of CTN fees is a PI responsibility. CTN acknowledgement from the TGA is only issued post payment.

For further information please refer to see Barwon Health Clinical Trial Sponsorship SOP.

Insurance and Indemnity

Barwon Health must be satisfied that sponsors of clinical trials have indemnity, insurance and compensation arrangements in accordance with applicable regulatory requirements.

The Victorian Managed Insurance Authority (VMIA) provides cover for Victorian public hospitals and the key risks associated with clinical research. Further information regarding the types and level of insurance and indemnity required can be obtained from the VMIA Clinical Trials Guidelines and NHMRC Insurance Guidelines.

Commercially Sponsored Trials

All commercially sponsored trials at Barwon Health must be indemnified and insured by an Australian sponsor, in accordance with the MA Standard Form of Indemnity for Drug Trials or the MTAA Standard form of Indemnity for Projects Involving a Device.

Where a trial is commercially sponsored, a certificate of currency for public and products liability must be submitted to RDU. A current insurance certificate must be kept on file and supplied to the RDU throughout the duration of an approved project.

Collaborative Group Research

Each party involved in a Collaborative Research Group (CRG) is liable for its acts and omissions in relation to the conduct of the research and must maintain insurance to provide indemnity to it in relation to any liability which it may incur. Some CRGs are registered as business entities and will provide a standard form of indemnity and evidence of insurance in the same manner as a commercial sponsor. Where this is the case the minimum requirements listed in the above section must be followed.

The nature of the CRG must be clear in any application to conduct research at Barwon Health. For example, public healthcare institution VMIA insurance usually covers the conduct of clinical trials, while Research Institutions must provide an insurance certificate.

Registration of Clinical Trials

The National Statement (section 3.1.7) requires researchers to ensure clinical trials are registered on a publicly accessible register complying with international standards outlined by the WHO International Clinical Trials Registry Platform (WHO ICTRP) prior to the recruitment of the first participant.

Registration of a clinical trial on a publicly accessible register such as ClinicalTrials.gov or Australian New Zealand Clinical Trials Registry (ANZCTR) is important to ensure improved research transparency,

to facilitate research participation and avoid duplication of effort. It can also aid the identification of evidence gaps and/or areas of unmet need, promote research collaboration and improve clinical research quality.

It is also a requirement of publication by the International Committee of Medical Journals Editors (ICMJE) that clinical trials are registered publicly prior to the enrolment of the first participant.

In some instances, other types of studies (i.e. non-Clinical Trials) may also need to be registered as a condition of funding.

It is the CPI/PI's responsibility to ensure clinical trials at Barwon Health are registered in a publicly accessible register prior to recruitment of the first participant, ensuring that information is accurate and complete and that the record is kept up-to-date. The language used in the general title and the lay summary of the registration record should be brief, clear, and written in plain English so that it is understood by a lay person prior to commencement of the trial and that adequate evidence of this registration is available on file.

Conflicts of Interest

Researchers must disclose and manage actual, potential or perceived conflicts of interest to proposed or ongoing research consistent with *the Code* and the NHMRC Disclosure of interests and management of conflicts of interest Guide (2019).

All Barwon Health researchers must be aware of and adhere with Barwon Health's Research Conflicts of Interest Policy which is in alignment with *the Code,* as well as Barwon Health's general Conflicts of Interest policy.

Additionally, Barwon Health researchers must be aware of and adhere with the Barwon Health Gifts, Benefits and Hospitality Policy, which is in alignment with the VIC Health Gifts, Benefits and hospitality policy.

Management of Data and Primary Materials

The proper management and retention of research data during the conduct, and after the completion of a research project, ensures a justification and defence of the research outcomes can be provided if results are challenged. This is a researcher responsibility under GCP. All research projects sponsored by Barwon Health should have a Data Management Plan (DMP) in place which sets out how data will be collected, managed and stored. Evidence of a satisfactory DMP may be a requirement of Governance Authorisation of Barwon Health sponsored projects.

Data and Primary Materials

Electronic Documents and Data

Barwon Health Researchers are required to store electronic documents and data on Barwon Health approved network or platform servers which are generally hosted on premise at Barwon Health. These servers are backed up at regular intervals and 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 as per Barwon Health Information Management Policy and Information Security Procedure. The latest version of the amended file or document must be saved to K drive or Sharepoint at the earliest opportunity. The Information Services department is responsible for maintaining network drives in workable order and for managing backup protocols.

Creating, managing and using information from research databases is the responsibility of the Sponsor (or Research Lead where Barwon Health is the sponsor). The Research Data Management Service is

able to provide support for design of databases and report creation on Barwon Health approved data management platforms.

REDCap

REDCap (Research Electronic Data Capture) is a secure web application for building and managing online surveys and databases. The system was developed by a multi-institutional consortium based at Vanderbilt University, but is hosted on Barwon Health Hospital servers and managed by the RDU.

While REDCap can be used to collect virtually any type of data, Barwon Health REDCap is only permitted to be used to support online or offline data capture for research studies (including clinical trials), Quality Improvement/Audits, as well as administrative and operational purposes. Please note REDCap is not designed to capture patient clinical data (is not an Electronic Medical Record). Data collection is customised for use (study or clinical operation) by the users. The RDU based REDCap administrator provides technical oversight and moves finalised data collection tools into production.

Barwon Health encourages its staff to use REDCap for research purposes as the data is held at Barwon Health and the system and security is managed in accordance with the Barwon Health Information Technology (IT) systems and protocols. All data collection, storage and use of REDCap must remain compliant with Barwon Health policies, guidelines, processes, regulations, project approvals, agreements and any other applicable requirement, irrespective of the data formats and tools used to collect and manage the data. It is the users' responsibility to be familiar and comply with these requirements. Where REDCap is used for clinical trial data management, users should develop and maintain fit-for-purpose Standard Operating Procedures to ensure that REDCap is being used appropriately, addressing matters including logging of activities, the processes for updating REDCap forms and ensuring alignment with HREC approved materials.

Barwon Health recommends that PIs maintain printed copies of REDCap forms to enable offline data collection and subsequent data entry if there is a need to collect data during an outage.

Laboratory Notebooks

The laboratory notebook and its contents are to be considered a confidential legal document of great value. Laboratory notebooks are legal documents recording a researcher's work in the laboratory. They are a complete record proving that the researcher conducted the research. This is important as many regulatory authorities (Food and Drug Administration – USA, Therapeutic Goods Administration in Australia) and the US and Australian patent offices and courts use laboratory notebooks to determine the validity of claims, establish ownership of inventions and dates of data entry in IP disputes.

Barwon Health uses hard copy laboratory notebooks (no online system). The notebooks are regularly dated and signed off by researchers and supervisors as proof of IP. We recommend use of notebooks with numbered pages.

Confidentiality and Privacy

It is essential that researchers maintain a participant's privacy, wherever possible, when collecting and using personal, health or sensitive information in a research project. 'Sensitive information' includes medical information as well as information about an individual's racial or ethnic origin or sexual orientation or practices, among other characteristics. Researchers must ensure that study data is stored securely during the project and after its completion.

All research involving the use of personal health information must abide by the requirements outlined in:

- Australian Privacy Principles

- Section 95A of the Privacy Act 1988 (Cth)
- Guardianship and Administration Act 2019
- Health Records Act 2014 (VIC)
- Public Health and Wellbeing Act (2008)
- Medical Treatment Planning and Decisions Act 2016 (Vic)
- National Statement
- The Code

The following points must be adhered to when designing a research project involving the collection, use and dissemination of participant information:

- An individual's data should only be viewed and/or collected if necessary to fulfil the aims of the research.
- Informed consent to collect, use, store and disseminate a person's information should be obtained wherever possible.
- If consent for use of data in a research project cannot be obtained from the participant, a person responsible or guardian/parent should provide consent on their behalf. If this cannot be done, a waiver of consent must be granted by an HREC.
- Data should be collected, used, stored and disseminated in a manner that protects the privacy of the participant.
- Data should be stored for an acceptable period in line with relevant state and federal legislation.
- If data is to be transferred to another organisation, wherever possible, it should be in a non-identifiable or re-identifiable format and the participant should consent to the third party obtaining the information. It is the researcher's responsibility to ensure that the third party complies with the Australian privacy standards when receiving data.

The following aspects should also be taken into consideration when considering the risks associated with data collection, use and retention:

- The nature of the data being collected, especially if it is sensitive, demographic or health information.
- The format that the data will be collected, used and stored, and whether it is identifiable, re-identifiable, non-identifiable or a mixture of all three.
- Location and length of time that the research data will be kept.
- The potential for data to be used in future research.
- If the data is to be transferred between organisations and how this will occur.
- The nature of consent obtained for the collection, use, sharing and storage of data.
- The data security measures in place to maintain confidentiality.
- If there are any risks associated with dissemination of results.

- Who within the research team is best placed to collect the data.

Data Sharing

Under the Privacy Act 1988, sensitive human and personal data cannot generally be shared in its original form. However, once non-identifiable, these modified data no longer fall under the Act as they are not 'personal information' which means that non-identifiable data can legally be shared (the OAIC De-identification Decision-Making Framework gives practical resources on how to de-identify datasets). Institutions, funding agencies and publishers are often encouraged, and in some cases require, non-identifiable research data to be shared.

The *National Statement* and *the Code* recognise the value of making research data available for future research and encourage researchers to make data available for use by other researchers unless it is prevented by ethical, privacy or confidentiality reasons. Researchers should abide by the requirements of the *National Statement* and the Australian Privacy Principles and any state and territory legislation as relevant.

For further information on data sharing useful sources of guidance also include the NHMRC Statement on Data Sharing and the ANDS: Guideline on Publishing and Sharing Sensitive Data.

Retention

Ultimately it is the researcher's decision as to which data and materials should be kept. In some cases this is determined by law, funding agency, publishers, and commercial sponsors, or by standard convention. For clinical trials, data must be retained for a minimum of 15 years for adult studies or 25 years for paediatric studies. For other research, data must be retained for 7 years for adult studies. For areas such as gene therapy, research data must be retained permanently. Data retention is a PI responsibility. Where a PI ceases employment at Barwon Health, they must ensure the PI responsibility for their research project is formally transferred to an existing Barwon Health research project team member, or their Department Research Lead via an ERM amendment submission. Transfer of PI responsibility, including oversight of research data, must occur before the last day of employment with Barwon Health.

Intellectual Property

The term Intellectual Property, or 'IP', refers to the various rights which the law accords for the protection of creative effort, and especially for the protection of the economic value of creative efforts. IP is 'intangible' as opposed to 'physical' in character.

In Australia, there are distinct statutory regimes regulating the four 'core areas' of IP

- Copyright
- Patents
- Registered designs and
- Trademarks

Patents include the following categories: Device, Substance, Method and Process.

The NHMRC has published a set of National Principles of Intellectual Property Management for Publicly Funded Research, which provides guidance on the ownership, promotion, dissemination, exploitation and, where appropriate, protection of IP generated through Australian Government funded research by public sector institutions.

Organisations undertaking research are required to have IP arrangements in place for employees. This is generally captured in either an employment contract, or in an IP Policy. It is the responsibility of a researcher to understand the basic principles of Intellectual Property, and to understand the policies and processes in place within their organisation for managing any IP assets that may be developed by staff in the course of their work.

All Barwon Health researchers must be aware of and adhere to the:

- Whole of Victorian Government Intellectual Property Policy, 2012
- Intellectual Property Guidelines for the Victorian Public Sector - Version 1.1
- Barwon Health Intellectual Property Research Policy

If you have any IP-related questions, please contact the Barwon Health Legal Counsel. legalservices@barwonhealth.org.au

Biospecimen Collection, Access, Use, Retention, and Disposal

The National Statement defines human biospecimen as any biological material obtained from a human including tissue, blood, urine, sputum and any derivative from these, such as cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person.

When designing research involving human biospecimens, researchers at Barwon Health should take into consideration the following ethical aspects:

- The way the human biospecimens are obtained
- The information that may be derived from human biospecimens
- The implications of that information for the individual donor, their relatives, and their community
- The significance that may be attached to the human biospecimens by individual donors and/or communities.

All research projects to be carried out in Barwon Health and affiliated facilities and involve any use of human biospecimens, must be reviewed and approved by the Barwon Health HREC before the research can commence. This includes also the establishment of biobanks.

Chapter 3.2. of the National Statement provides detailed guidance to HRECs and researchers on the aspects and levels of ethical review depending on the nature of research. It emphasises the importance of obtaining consent, collection, processing, storage and distribution or disposal of human biospecimens.

The collection of biospecimens in Victoria is regulated by the Victoria's Human Tissue Act 1982 and specifies the conditions for the removal of human tissue, such as blood and organ donation from the living people, the donation of organs and tissue after death, post mortem examinations and the prescription of tissue banks.

The transfer of human biospecimens between Barwon Health and an external biobank or vice versa should be covered under a Material Transfer Agreement (MTA). MTA is a legal agreement between two parties that is used to define the terms and conditions under which materials may be transferred from one party to the other.

Genomics Research

If the research involving human biospecimens is of a genetic nature, the researchers should ensure that they are also familiar with and follow the guidance of the Chapter 3.3 of the National Statement: Genomic Research. It covers the information about the generation, collection, access, analysis,

disclosure, storage, retention and use of genomic data and information that has hereditary implications and/or is predictive of future health in research involving participants, relatives and other family members.

Biobanks

All biobanks at Barwon Health must be approved by the HREC. Specifically, this means that they must comply with Chapter 3.2. of the National Statement : Human Biospecimens in laboratory-based research. Any biobanks that intend to use biologicals must also comply with relevant regulatory requirements such as the Therapeutic Goods Administration (TGA), Office of the Gene Technology Regulator (OGTR) and any relevant state and federal laws.

For any questions related to research involving biospecimens or biobanks please contact the Research Development Unit at RDU@barwonhealth.org.au.

Safety Monitoring & Reporting of Human Research

Institutions are responsible for ensuring that any human research they undertake is conducted in accordance with *the Code* and ethically approved and monitored in accordance with the guidance of the *National Statement* and HREC approved protocol.

Under section 5.5 of the *National Statement*, monitoring refers to the process of verifying that the research is being conducted in accordance with the approved proposal. Mechanisms for monitoring can include:

- Reports from researchers.
- Reports from Independent agencies (such as data and safety monitoring boards).
- Review of safety reports.
- Random inspection of research sites, data or consent documentation.
- Interview with research participants or other forms of feedback.

The frequency and type of monitoring will depend on the degree of risk to the research participants, the researcher and the institution (also see NHMRC publication Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods 2018).A key principle is that studies should have a detailed Risk Management Plan, which then informs the Monitoring Plan.

All research is monitored for compliance with policy, legislation and procedures to ensure systems are in place for the management of complaints, including research misconduct and fraud.

The Victorian Department of Health webpage for monitoring and reporting on an approved research project includes templates for reporting to HREC and institutions. These forms are also located within ERM. For all research projects granted Research Governance Authorisation at Barwon Health, the RDU must be notified of any new information that might warrant further review of authorisation of the project. In addition, the RDU must be provided with annual progress reports, as well as a final report at the completion of the project via ERM (copies of reports submitted to the approving HREC can also be provided to the RDU as attachments within ERM)

See RDU website: Project Monitoring

See Barwon Health Research Governance SOP for further information.

Reporting Safety Events

Barwon Health outlines its safety reporting requirements in the Barwon Health Research Safety Monitoring and Reporting Guideline (2021) which aligns with the NHMRC publication, Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016), that sets out the requirements for the monitoring, collection and reporting of adverse events and adverse reactions that occur in clinical trials involving investigational medicinal products (IMPs) and investigational medical devices (IMDs). The guidance is also broadly applicable to all clinical trials involving therapeutic goods.

This NHMRC publication defines the roles and responsibilities of the sponsor, researchers, institution and HREC in terms of reporting and managing of the below safety events.

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

It should be noted that safety data collection and reporting responsibilities attributable to Barwon Health as a clinical trial investigator site may be different for a clinical trial depending on the recipient, i.e., the Sponsor, HREC, Research Governance Officer (RGO), TGA. For example the Sponsor but not the HREC or RGO may require the investigator site to collect and report all Adverse Events.

The information provided in the Barwon Health Research Safety Monitoring and Reporting Guideline (2021) and the Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) publication should be considered best practice for all research projects and applied to non-clinical trials where applicable. Under the National Clinical Trial Governance Framework, Research Safety Reporting intersects with Clinical Safety reporting via Riskman Reports, research department liaison with Barwon Health Safety Quality and Improvement Department and reporting through Consumer Experience and Clinical Governance Committee (CECG).

The Barwon Health Management and Reporting of Safety Events SOP provides further information on this process at Barwon Health.

Data Safety Monitoring

The NHMRC publication Guidance on Data Safety Monitoring Boards (DSMB) 2018 outlines the role, function and composition of an independent DSMB where required. DSMBs are established by the trial sponsor or relevant responsible body to review at regular intervals, accumulating trial data, in order to monitor the progress of a clinical trial. A DSMB is one of a range of mechanisms available to sponsors to mitigate trial risks and every trial must identify the most appropriate mix of monitoring activities according to a risk based model (also see NHMRC publication Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods 2018).

Where appropriate alternative non-DSMB safety monitoring structures may be put in place (i.e. for low-risk trials) which may include oversight by a Trial Management Committee, Trial Steering Committee and/or use of an independent Medical Monitor.

Risk-based monitoring and oversight activities should be considered as early as possible in the trial design phase. For IITs it is important that funding is sought which covers the cost of this activity (i.e. considered in grant applications or funding agreements).

Where Barwon Health is intended to be the Sponsor of a Clinical Trial conducted under the CTN scheme researchers should contact the RDU as early as possible to discuss requirements and options for monitoring arrangements.

Reporting Serious Breaches of GCP

The NHMRC Reporting of serious breaches of Good Clinical Practice (GCP) or the protocol for trials involving therapeutic goods (2018) sets out the requirements for reporting serious breaches that occur in clinical trials.

A protocol deviation is any breach, divergence or departure from the requirements of GCP or the clinical trial protocol. GCP requires all deviations to be reported to, and collated by the Sponsor. The term serious breach describes the subset of deviations that are likely to affect to a significant degree:

- The safety or rights of a trial participant
- The reliability and robustness of the data generated in the clinical trial.

See Barwon Health SOP for Management Serious Breaches of GCP.
See Barwon Health Research Safety Monitoring and Reporting Guideline (2021)

Other Types of Research

Authority to Prescribe Drugs of Addiction in Research

In accordance with the Drugs, Poisons and Controlled Substances Act 1981 and the Drug Poisons and Controlled Substances Regulations 2017, researchers (medical practitioners or nurse/midwife practitioners) planning to prescribe or supply any of the following in Victoria for the purposes of research must obtain authority from the Victorian Ministry of Health.

- A substance in Schedule 8 (S8) of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), including a cannabis medicine, an unregistered medicine or an extemporaneously-compounded medicine
- A substance in Schedule 9 (S9) of the SUSMP
- Dangerous Goods (Transport by Road or Rail) Regulations 2018 (VIC)

Researchers must have an authority to prescribe and/or supply in place before Research Governance Authorisation can be granted for these types of research projects. For a researcher to prescribe and/or supply these drugs at Barwon Health, it is a requirement of Barwon Health that the researcher be an employee.

Further information can be found on the Victoria's Department of Health Website - Drugs, Poisons and Controlled Substances Act 1981 and Regulations 2017

Use of Genetically Modified Organisms

Gene technology (also referred to as genetic engineering, biotechnology or genome editing) is defined in the Gene Technology Act 2000 (the GT Act) as any technique for the modification of genes or other genetic material, but does not include: a) sexual reproduction; b) homologous recombination; or c) any other technique specified in the Regulations that is not gene technology.

The use of genetically modified organisms (GMOs) and other non-GMO biological hazards must be conducted in compliance with the GT Act, the Gene Technology Regulations 2001 and Australia New

Zealand Standards Safety in laboratories standard AS/NZS 2243.3. Institutions and individuals must comply with the act and regulation. Sanctions apply where there is failure to comply.

The Gene Technology Regulator through the Office of the Gene Technology Regulator (OGTR) is responsible for administering the GT Act as well as the corresponding state and territory legislations. The OGTR has specific responsibilities in protecting the health and safety of people and the environment through identifying risks posed by gene technology and managing those risks through regulating certain activities/dealings. (See Risk Analysis Framework 2013).

Dealings with GMOs are prohibited unless:

- The person undertaking the dealing is authorised by a GMO licence:
  - DIR: Dealings that involve intentional release of a GMO into the environment,
  - DNIR: Dealings that do not involve intentional release of a GMO into the environment,
  - Inadvertent dealings (dealings where a person has come into contact with a dealing without realising or intending to),
  - Emergency Dealing Determination (EDD) (approval of dealings with a GMO in an emergency),
  - Notifiable Low Risk dealings (NLRD)
- The dealing is an exempt dealing (as per schedule 2 of the GT Act); or
- The dealing is included in the GMO Register.

Where the dealing requires a licence, the OGTR must provide authorisation before the activity can commence. A list of all approved GMO dealings can be accessed on the OGTR's GMO dealings webpage. Accreditation of the licence holder under the GT Act is also often a condition of the licence. Dealing with a GMO without appropriate authorisation under the GT Act is an office and subject to criminal penalties.

Institutional Biosafety Committees (IBCs) evaluates exempt and low-risk dealings and review licence applications for higher risk dealings before the applications are sent to the Regulator.

Deakin University IBC is nominated as the Barwon Health associated IBC.

Barwon Health is an accredited organisation (accreditation number Accr-222) and meets obligations and responsibilities under the Gene Technology Act, including performing GMO Clinical Trials. Barwon Health currently accepts IBC reports for multi-site GMO Clinical Trials from commercial company IBCs and other healthcare institution IBCs.

Researchers must seek Senior Research Governance advice by contacting REGI@barwonhealth.org.au at feasibility stage, before commencing GMO clinical trial governance submission to RDU. Researchers may also need to consult with Research Directorate Laboratory Manager.

Clinician-instigated research that involves working with GMOs in a laboratory setting at Barwon Health requires the project to be approved by Deakin University's IBC. Barwon Health operates an OGTR certified PC2 laboratory (certification no. Cert-4003), the operation of which is audited annually by Deakin Biosafety. Certification requires appropriate physical design and maintenance of the laboratory

space, in addition to appropriate training of staff in laboratory practices. Standard operating procedures relevant to working with GMOs are maintained on PROMPT.

Research Involving Animals

All activities that involve the use of an animal for scientific purposes within Victoria must be approved by an Animal Ethics Committee (AEC) before commencing. This is in compliance with the Victoria Prevention of Cruelty to Animals Act (1986), Prevention of Cruelty to Animals Regulations 2019 and the Australian code for the care and use of animals for scientific purposes 8th Edition 2013 (updated 2021) (*Animal Code*).

AEC review, approval and ongoing oversight ensures animal use

- Has scientific or educational merit
- Is ethically acceptable (potential effects on the wellbeing of the animal is justified by the potential benefits to humans, animals or the environment)
- Is conducted with integrity and that the principles of the 3Rs (replacement, reduction and refinement) are adhered to.

All procedures and quantity of animals to be used in a research project must be approved by the AEC, any variation to the information originally provided must be submitted to the AEC as an amendment. In addition, the AEC must be provided with annual progress reports, as well as a final report and any adverse events that occur during the course of the project.

In addition, organisations or individuals wanting to conduct scientific procedures with animals in Victoria must hold a Scientific Procedures Premises Licence (SPPL) issued by Animal Welfare Victoria. Activities must be conducted in compliance with the SPPL and have AEC approval.

Any variations to facilities and/or AECs to which the organisation reports must be submitted to Animal Welfare Victoria as a variation to the SPPL. Researchers are also responsible for recording animal usage which Barwon Health is required to report annually to Animal Welfare Victoria.

Currently, Barwon Health does not have the infrastructure, SPPL licence, nor an AEC to support the conduct of research involving the use of animals. However, if you are interested in conducting this type of research, please contact RDU to discuss collaborating with our University partners.

Research Involving Human Embryos

Research activities that involve the use of human embryos created by assisted reproductive technology (ART) or by other means must be conducted in compliance with the Research Involving Human Embryos Act 2002 (RIHE Act), the Prohibition of Human Cloning for Reproduction Act 2002 (PHCR Act), Research Involving Human Embryos Regulations 2017 (RIHER), Research Involving Human Embryos Act 2008 (VIC), Prohibition of Human Cloning for Reproduction Act 2008 (VIC), Assisted Reproductive Treatment Act 2008 (VIC).

The NHMRC Embryo Research Licensing Committee (NHMRC Licensing Committee) is established by the RIHE Act and regulates research activities that involve the use of human embryos.

Research involving human embryos can only be conducted if authorised by a licence issued by the NHMRC Licensing Committee. A list of all licences issued by the NHMRC Licencing Committee authorising use of excess ART embryos is publically available on the NHMRC website.

Licensable activities include:

- Any use of an excess ART embryo which is not an exempt use as specified in subsection 10(2) of the RIHE Act,
- Research or training in ART involving fertilisation of a human egg by a human sperm outside the body of a woman,
- Establishing a new human embryonic stem cell line from excess ART embryos or other embryos; or
- Other activities as specified in the legislation.

Researchers must be familiar with the legislative and regulatory requirements. Information on the NHMRC Embryo Research licence application process and regulatory framework are provided on the NHMRC – Information for applicants webpage. HREC approval must be in place before applying for a licence.

If your project involves the use of human embryos please contact the RDU as early as possible to discuss.

Research Involving the Use of Ionising Radiation

All research involving exposure of persons to ionising radiation above standard of care must be carried out in accordance with The Code of Practice – Exposure of Humans to Ionizing Radiation for Research Purposes Radiation Protection Series Publication No. 8 (RPS 8) set out by Australian Radiation & Nuclear Safety Agency (ARPANSA Code). In addition, the Victorian Department of Health regulates the use of radiation to protect people and the environment from its harmful effects by administering the Radiation Act 2005 and the Radiation Regulations 2017, that are made under section 139 of the Act. Under the Act, the users of radiation equipment and managers of radiation practises should be licenced. Radiation Management Licences are issued by the Department of Health.

Compliance with RPS8 is required as a Management Licence condition for the Barwon Health Radiation Management Licence.

Before submitting a research project for ethics and governance review and authorisation involving the administration of ionising radiation (to research participants), the researcher must be familiar with their roles and responsibilities as outlined under the ARPANSA Code and the relevant Victorian regulations. Researchers must also be familiar with, and follow the processes of the Barwon Health guidelines on Research Involving Radiation and the Code of Practice for Exposure of Humans to Ionizing Radiation for Research Purposes

More information can be found on the RDU Website: Barwon Health Research Involving Radiation

If you have any questions, you can contact the Barwon Health Radiation Safety Officer RSO@barwonhealth.org.au

Resource Management

Good financial management practice requires researchers to ensure that they have adequate funding to undertake their study and therefore have a likelihood of delivering the outcomes of their project.

A study budget identifies the obvious costs of the research activity (e.g. estimated staff time, capital equipment, review fees, statistical analysis, software, participant tests, database management, r, human biospecimen etc.) in addition to regular participant intervention, as well as in-kind support.

Where applicable a study budget must be included in the Research Agreement and will outline all the relevant costs or grant application.

Where research activity undertaken by Barwon Health (commercially sponsored or otherwise) involves the contracting or subcontracting by Barwon Health of research-related clinical services, Barwon Health will engage the services of third parties consistent with its service arrangements for contracting of clinical services.

Barwon Health Departments engaging third party research finance management from entities such as Clinical Trials Australia (CTA) remain responsible for RDU Review Payments.

If you have any questions, you should contact the RDU for advice.

Funding Sources

Funding support for a research project can come from a variety of sources and may take many forms. This includes, but is not limited to:

- From a commercial sponsor
- In kind support or donated time from researchers, departments, laboratories or Collaborators.
- Donated investigational products from commercial entities.
- Grant funding from Barwon Health, commercial entities, government agencies such as the NHMRC and other not for profit organisations.

Any form of funding arrangement for the conduct of research at Barwon Health must have an appropriate and transparent financial management process in place. Any conflicts of interest must be declared before research commencement, as part of the ethical and governance review process where appropriate (see also Research Conflicts of Interest Policy).

Resource Support and Service Provisions

If a research project requires resources to be allocated from departments or providers outside of the researcher's area of direct reporting, the researcher must negotiate the terms of the service provision with a responsible party. The researcher must also obtain written support from the director of the department/provider before the project commences (See Instrument of Delegation Policy).

External Service Provider Agreements

The PI is responsible for ensuring an appropriate Service Agreement is in place when using an external service provider for any study related activities (i.e. a Service Agreement designed for the procurement of a service for a clinical trial or research study, without the Service Provider being a Site).

PI Oversight of Third Parties

For Clinical Trials, the PI must be able to demonstrate oversight and approval of third parties and any sub-contracted duties in accordance with ICH-GCP (section 4.2.6 annotated by the TGA). The PI has responsibility for ensuring all third parties are appropriately qualified/accredited and will obtain and keep copies of relevant accreditation/certification/ licenses (e.g. to manufacture/distribute medicinal product), requesting and taking up references or remote/on-site audit.

For research at Barwon Health the PI is required to obtain approval from the study Sponsor prior to engaging any third parties at the feasibility/ start-up/risk assessment stage of the trial. The PI should also confirm whether the budget is in place, or has been applied for, to cover all third party activities.

In these instances the PI is required to ensure:

- All relevant documentation is provided to the third party in a timely manner i.e. research protocol, approved protocol amendments, associated documentation and copies of required approvals.
- No activities are implemented by the third party until appropriate approval and contracts are in place.
- Maintain regular contact with the third party/parties. Key correspondence and meeting minutes will be retained in the Investigator Study File (ISF).
- Advise the third party of any protocol amendments that may impact the services that the third party has been engaged to provide.

Research Agreements

Where a project involves Barwon Health and another organisation (i.e. Commercial Sponsor, Contract Research Organisation (CRO), institute, hospital or Collaborative Research Group (CRG)), an agreement on the management of the research must be in place before the project can be authorised to commence. Any such agreement is to be approved within the Barwon Health Instrument of Delegation

This agreement must be in writing and include:

- The intellectual property rights
- Confidentiality and copyright issues
- Sharing commercial returns
- Management of conflict of interest
- Insurance and indemnity arrangements
- Responsibility for ethics and safety clearances and reporting to appropriate agencies
- Protocols to be followed when disseminating the research outcomes
- Management of primary research materials and research data
- Budget and Payment arrangements

Research Agreement Types

The type of research activity undertaken and the nature of the relationship between collaborating parties will determine the most appropriate contractual agreement.

Commercially sponsored trials must use the Medicines Australia (MA) Clinical Trial Research Agreement (CTRA) or Medical Technologies Association of Australia (MTAA) Standard Clinical Investigation Research Agreement (CIRA) for research involving investigational medicinal products or devices, respectively.

For investigator-initiated and collaboration group research, a number of approved standard agreements can be used. The type of research agreement will depend on the nature of the trial and the parties involved.

Please refer to the Barwon Health Research Agreements Guide

Authorship and Research Outputs

Barwon Health 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 (See also Intellectual Property Research) In accordance with *the Code*, Researchers are responsible for:

- Disseminating their research findings responsibly, accurately and as broadly as possible (R23),
- Ensuring appropriate and fair attribution of authorship to those who have made a significant contribution to the research and its output, and that all authors have agreed to be listed as authors in publications (R25), and
- Acknowledging contributions other than authorship (R26).

The Barwon Health Guidelines on Collaborative Research and Authorship provides further guidance in accordance with the Code and the supporting NHMRC Publication and Dissemination of Research Guide (2020) and the NHMRC Authorship Guide (2019).

Barwon Health Library

Barwon Health Research Publications

Evaluation

Regular document revision and review of quarterly research reports. These evaluations need to be applied when the document is reviewed.

Key Aligned Documents

Financial Management Policy

Governance Policy

Operational Service Delivery Policy

Research Governance Framework

Research Policy

Safety & Quality Policy

Workforce Policy

Research Governance Framework

Research Strategic Plan

Research Conflicts of Interest Policy

Information Management Policy

Barwon Health Intellectual Property Research Policy

Instrument of Delegation Policy

Key Legislation, Acts & Standards

All Barwon Health policies, frameworks, procedures, guidelines and TORs can be found on Prompt.

Below is a list of external references and resources.

References & Resources (Appendix 1)

Theme	Reference	Category
	The Australian Code for the Responsible Conduct of Research, 2018 (the Australian Code)	Code
	Supervision – A guide supporting the Australian Code for the Responsible Conduct of Research	Guidance
	Australian Clinical Trials Toolkit	Resource
	Investigator-Initiated Trials Toolkit	Resource
	GCP providers – TransCelerate recognised.	Resource
	ICH Guideline for Good Clinical Practice – Annotated with TGA comments	Standard
	ISO 14155:2020 Clinical investigation of medical devices for human subjects – Good clinical practice	Standard
	ISO 9001:2015 Quality management systems — Requirements	Standard
	ISO/IEC 27001 and related standards Information security management	Standard
	The National Clinical Trials Governance Framework and User Guide for Health Service Organisations Conducting Clinical Trials	Guidance
Project Design	SPIRIT Statement	Guidance
	The James Lind Alliance	Guidance
	Statement on consumer and community involvement in health and medical research	Guidance
	Consumer and community engagement (includes links to additional references/toolkits)	Guidance
	Consumer Involvement and Engagement Toolkit	Templates
	Peer Review	Guidance
Funding	NHMRC Funding research	
	Australian Research Council	
Human Research Ethics	National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)	Guidance

	AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (AIATSIS code), 2020	Code
	Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders, 2018	Guidance
	A Guide to applying The AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research	Guidance
	Keeping research on track II. A companion document to Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders	Guidance
Animal Ethics	The Prevention of Cruelty to Animals Act (1986)	Legislation (Vic)
	Prevention of Cruelty to Animals Regulations 2019	Regulation (Vic)
	Animal Welfare Victoria	Authority
	Australian code for the care and use of animals for scientific purposes 8th Edition 2013 (updated 2021)	Code
	Australian code for the care and use of animals for scientific purposes 8th Edition 2013 (updated 2021)	Guidance
	Best practice methodology in the use of animals for scientific purposes 2017 (updated July 2018)	Guidance
	Guidelines to promote the wellbeing of animals used for scientific purposes	Guidance
	Australian & New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART)	Guidance
Data and Primary Materials Management	Privacy Act 1988	Legislation (Cth)
	Privacy Regulation 2013	Regulation (Cth)
	Office of the Australian Information Commissioner (OAIC)	Authority
	Australian Privacy Principles quick reference	Guidance
	List of State and Territory Privacy Laws	Guidance
	Guidelines under Section 95 of the Privacy Act 1988	Guidance
	Guidelines approved under Section 95A of the Privacy Act 1988.	Guidance
	Privacy and Data Protection Act 2014	Legislation (Vic)
	Guardianship and Administration Act 1986. Act Number 58/1986	Legislation (Vic)
	Guide to the legislation relating to the provision of consent for an adult with impaired capacity to provide informed consent to participate in the conduct of human research	Guidance

	NHMRC Management of data and information in research	Guidance
	Health Records Act 2001	Legislation (Vic)
	Human Tissue Act 1982	Legislation (Vic)
	Ethical and Legal Issues in Relation to the Use of Human Tissue in Australia and New Zealand	Guidance
	International Air Transport Association Dangerous Goods Regulations (IATA DGRs)	Guidance
	Civil Aviation Act 1988	Legislation (Cth)
	Civil Aviation Safety Regulations 1998 Statutory Rules No. 237	Regulation (Cth)
	CASR part 92 – Consignment and carriage of dangerous goods by air (including part 92 advisory documents)	Authority - Guidance
Therapeutic Goods Administration	Therapeutic Goods Act 1989	Legislation (Cth)
	Therapeutics Goods Regulations 1990	Regulation (Cth)
	Therapeutic Goods (Medical Devices) regulation 2002	Regulation (Cth)
	Therapeutic Goods Administration (TGA) – Clinical Trials	Authority
	TGA Clinical Trials Handbook	Guidance
	TGA – legislation & Legislative instruments	Guidance
Medicines and poisons Controlled Substances	Drugs, Poisons and Controlled Substances Act 1981 Department of Health & Human Services (Vic)	Legislation (Vic) Authority (Vic)
Gene Technology	Gene Technology Act 2000	Legislation (Cth)
	Gene Technology Act 2001	Legislation (Vic)
	Gene Technology Regulations 2001 (current compilation)	Regulation (Cth)
	Gene Technology Regulations 2011	Regulation (Vic)
	Office of the Gene Technology Regulator	Authority
	Guidelines and checklists for certification of PC2 facilities	Guidance
	Risk Analysis Framework	Guidance
	Requirements under the Gene Technology Act 2000 for clinical trials in humans involving GMOs – Guidance for clinical trial sponsors	Guidance
	Risk Groups and Safety Levels of GMOs	Guidance

Embryo Research	Research Involving Human Embryos Act 2002 (RIHE Act)	Legislation (Cth)
	Prohibition of Human Cloning for Reproduction Act 2002 (PHCR)	Legislation (Cth)
	Research Involving Human Embryos Regulations 2017	Regulation (Cth)
	Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2017 (the ART Guidelines)	Guidance – Ethics
	NHMRC Embryo Research Licensing Committee	Authority
	Information for applicants webpage	Guidance
	Embryo Research Licensing Committee information kit	Guidance
	Objective criteria on embryos that are unsuitable for implantation	Guidance
	Instructions for completing the embryo research licence application form	Guidance
	Consent Checklist for licensed activities using excess ART embryos	Guidance
	Additional Information on obtaining consent	Guidance
	Research Involving Human Embryos Act 2002 Embryo Research Licensing Committee of the NHMRC – Standard Conditions of Licence	Guidance
Ionising Radiation	Radiation Act 2005	Legislation (Vic)
	Radiation Regulations 2017	Legislation (Vic)
	Victoria Department of Health - Radiation	Authority (Vic)
	ARPANSA Code of Practice – Exposure of Humans to Ionizing Radiation for Research Purposes RPS 8	Guidance
Research Agreements, Insurance and Indemnity	Medicines Australia Clinical Trial Research Agreements	Templates
	Medicines Australia Indemnity & compensation Guidelines	Templates
	Medical Technology Association of Australia - Clinical Investigation Research Agreements	Templates
	Collaborative Research – A guide supporting the Australian Code for the Responsible Conduct of Research	Guidance
	Indemnity and insurance arrangements for clinical trials	Guidance
Safety Monitoring and Reporting of Research	NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods November 2016	Guidance
	Risk-based management and monitoring of Clinical Trials involving therapeutic Goods 2018	Guidance
	Data Safety Monitoring Boards	Guidance

	Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving therapeutic Goods 2018	Guidance
	Monitoring and Reporting – monitoring and verifying the ethical conduct and safety of an approved research project	Guidance (Vic)
Research Complaints and Misconduct	Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research 2018	Guidance
Publication, Authorship & Communications	Publication and dissemination of research - A guide supporting the Australian Code for the Responsible Conduct of Research 2020	Guidance
	Authorship: A guide supporting the Australian Code for the Responsible Conduct of Research 2019	Guidance

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References

As above

Contributors

	Name	Position	Service / Program
Document Owner:	Lisa Fry	Manager, Research Development Unit	Research Directorate
Lead Reviewer:	Ajai Verma	CMO	Research Directorate
Contributors:	Lisa Fry Yordanka K Jason Hodge Alex Merchant Richard Larsen Natasha Savvides	Manager, RDU Chrysalis Consulting HERB Laboratory Manager Radiation Safety Officer Research Ethics Officer Research Quality Manager	Research Directorate
Committee/s:	Members	Research Management Committee	24.5.23

Abbreviations (Appendix 2)

Abbreviation	Definition
AEC	Animal Ethics Committee
ANDS	Australian National Data Service
ARPANSA	Australian Radiation & Protection Nuclear Safety Agency
ARTG	Australian Register of Therapeutic Goods
ART	Assisted Reproductive Technology
CIRA	Clinical Investigation Research Agreement
CRG	Collaborative Research Group
CRO	Contract Research Organisation
CTA	Clinical trial notification
CTN	Clinical trial approval
DoH	Department of Health (Victoria)
DIR	Dealings that involve intentional release of a GMO into the environment
DMMP	Data and primary material management plan
DNIR	Dealings that do not involve intentional release of a GMO into the environment
DSMB	Data Safety and Monitoring Board
HREC	Human Research Ethics Committee
IBC	Institutional Biosafety Committee
IIT	Investigator Initiated Trials
ICMJE	International Committee of Medical Journals Editors
IMD	Investigational Medical Device
IMP	Investigational Medicinal Product
IP	Intellectual Property
ISO	International Organisation for Standardisation
MA	Medicines Australia
MTAA	Medical Technologies Association Australia
NCTGF	National Clinical Trials Governance Framework
NHMRC	National Health and Medical Research Council
OGTR	Office of Gene Technology Regulator (OGTR)
PICF	Participant Information and Consent Form
PPE	Personal Protective Equipment
RGF	Research Governance Framework
RIHE Act	Research Involving human Embryos Act 2002 (RIHE Act)
RIHER	Research Involving Human Embryos Regulations 2017
RGO	Research Governance Officer
SAEs	Serious Adverse Events
SARs	Serious Adverse Reactions
SSI	Significant Safety Issues
SOP	Standard Operating Procedure
TGA	Therapeutic Goods Administration
USADE	Unanticipated serious adverse device effects
USM	Urgent Safety Measure

Abbreviation	Definition
VMIA	Victorian Managed Insurance Authority
WHO	World Health Organisation
WHO ICTRP	WHO International Clinical Trials Registry Platform