Department of Health

CLINICAL QUALITY, REGULATION AND ACCREDITATION

Tasmanian Government

Research Governance Policy Framework

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Routine Disclosure:	Yes

1. Policy Statement

- The *Research Governance Policy Framework* (*RGPF*) is the principal Policy framework that the Tasmanian public health system, inclusive of the Tasmanian Department of Health (DoH), the Tasmania Health Services (THS) and the associated service delivery centres must comply to ensure that the conduct for all human research activities are appropriately reviewed, authorised, conducted, monitored and governed.

2. Purpose

- The *RGPF* provides the governance framework to ensure that the conduct and management of all human research activities comply with applicable legal, regulatory and institutional requirements, appropriate ethical and scientific standards, and standards of quality, safety, privacy, risk management and financial management and monitoring requirements.
- The *RGPF* mandates all human research activities where the conducted of the research is proposed must undergo research governance review through a site-specific assessment process and be granted formal site authorisation in writing by the Chief Executive (equivalent or delegate).
- The *RGPF* ensures all personnel involved in research activities share responsibility and accountability for all human research activities being conducted are fully understood, enacted and maintained and in accordance with legal, regulatory, institutional and ethical and scientific standards within the levels of the public health services' delegation and risk framework.

- The *RGPF* ensures that a research governance framework integrates human research activities into routine healthcare delivery to enable the public health system to adapt to the changing health needs and requirements of the community and has social and economic benefits for consumers through improved health outcomes, and outcomes are communicated to the community.
- The *RGPF* ensures that human research fosters innovation and is promoted as a valued activity in the public health system and seeks to promote a culture of responsible research practice that protects and respects the rights of researchers and participants.
- The *RGPF* is underpinned by the *Research Governance Procedures* (*RGP*) and *Research Governance Documents* that all human research activities must be reviewed, authorised, conducted and monitored, giving a consistent and streamlined approach to research governance that can be monitored and evaluated for quality assurance and quality improvement.

3. Scope

- The *RGPF* is the overarching Policy framework for the Tasmanian public health system, inclusive of the Tasmanian Department of Health (DoH), the Tasmania Health Services (THS) and all the associated health service delivery centres.
- The *RGPF* applies to all staff, officers, volunteers, contractors; external individuals, organisations, entities, bodies or institutions (e.g. commercial, non-commercial sponsors and tertiary institutes) that propose to conduct, manage, review and govern research that requires the use of Tasmanian public health system facilities, access to participants (patient and/or public health service employees) and/or their data (medical and personal records of information) and/or tissue collections held within the authority of the Tasmanian public health system.
- The *RGPF* does not apply to these activities:
    - Animal research.
    - Quality Improvement (QI)/Quality Assurance (QA) activities involving audit and monitoring that aim to improve the 'quality of service delivered by an individual or an organisation'.
    - Business planning and evaluation of services to meet mandatory reporting obligations required by legislation or funding agreements; infrastructure and services planning; and co-design.

4. Mandatory Requirements

- This is a State-wide policy and must not be re-interpreted so that subordinate policies exist. Should discrete operational differences exist, these should be expressed in the form of an operating procedure or protocol.
- **Failure to comply with this policy**, without providing a good reason for doing so, may lead to disciplinary action; and, in serious cases, termination of employment or engagement.
- For investigators, failure to comply with this policy may lead to suspension or early termination for the conduct of the research project.

5. Roles and Responsibilities/ Delegations

- **Governing/Peak Body (or equivalent)** – is responsible for providing leadership, strategic direction and ensuring the overall effective and responsible conduct of human research and ensuring there are appropriate governance structures for the provision of safety and high-quality human research activities within the Tasmanian public health system.

- **Department of Health (DoH)** – is responsible for providing policy leadership to ensure that the conduct of human research activities is complaint with applicable legal, regulatory and institutional requirements; appropriate ethical and scientific standards; standards of quality, safety, privac; and professional standards; and monitoring and reporting on research activities within the Tasmanian public health system.
- **Chief Executive (CE)/Chief Executive Officer (CEO) (or equivalent)**– is responsible for ensuring adequate resources and structures are in place for effective research governance to meet the requirements this policy directive and national safety standards; and promote and support a culture of safety and high-quality for research activities within the DoH and THS.
- **Executive Director/Director (or equivalent)** – is responsible for ensuring compliance with this policy directive; and promote and support a culture of safety and high-quality in the conduct of research activities conducted at their public health service site.
- **Research Director (and/or Manager**)– is responsible for promoting a culture of safe and high-quality research through the promotion and awareness of this policy directive and national safety standards for research activities within the THS.
- **Research Governance Officer/s (or equivalent)** – is responsible for the efficient coordination and review of research governance applications in accordance with applicable legal, regulatory and institutional requirements; providing advice to staff and researchers; and utilising an ICT/database system to manage research activities within THS in accordance with this policy directive.
- **Heads of Department/Divisional Director/Supporting Department (or equivalent)** – is responsible for the financial oversight, including budget negotiation and ensuring there are sufficient resources and facilities within their Department/Division/Service Area to conduct research activities in accordance with this policy directive.
- **Business Manager** – is responsible for providing financial advice to the investigator, including budget negotiation and providing advice to the Head of Department/Divisional Director/Supporting Department within their Department/Division/Service Area to ensure any financial impact to conduct research activities is managed in accordance with this policy directive.
- **Coordinating Investigator/Principle Investigator (or equivalent)** – is responsible for the overall conduct, management and reporting of the project at a public health service site; submitting ethics and governance documentation; and ensuring that the conduct of research project is in a manner that is consistent with the protocol and this policy directive.
- **Associate Investigator/Clinical Trial Coordinator (or equivalent)** - is responsible for supporting the submission of the ethics and governance documents as delegated and conducting research projects in accordance with the agreed protocol, legal, regulatory and institutional requirements and this policy directive.
- **Sponsor –** is responsible for the initiation, management and financing (or arranging the financing), medico-legal responsibility associated with the conduct and the monitoring of research project at the nominated public health service site in accordance with this policy directive.
- **Participant/Patient –** is responsible for providing their consent to participate in the research project and providing feedback, complaints and compliments to the public health service.

Additional roles and responsibilities for personnel involved in the conduct, review, authorisation and monitoring of human research are listed in Appendix 1.

6. Glossary and Definitions

- Abbreviations and definitions are listed in Appendix 2.

7. Legislation and Safety & Quality Frameworks

- Relevant state and federal legislation and safety and quality frameworks are listed in Appendix 3.

8. References, Documents and Policies

- Relevant documents (internal and external) are listed in Appendix 4.

9. Attachments

- Research Governance Procedures
- Research Governance Documents

10. Development and Consultation

Stakeholder Group	Liaison Officer	Date
THS Integrated Quality Patient Safety	Chair	August 2019
THS – South Research Committee	Chair	September 2019
THS Research and Clinical Trials Working Group	Chair	September 2019
THS Legal Compliance and Policy Committee	Chair	October 2019

11. Approval

Review	Name	Position	Contact	Date
Prepared by	Tanya Harley	Research Governance – Project Coordinator	6166 0395	1 July 2019
Through	Dr Jodi Glading	Deputy Chief Medical Officer	6166 0413	1 Sept 2019
Through	Prof Anthony Lawler	Chief Medical Officer	6166 1015	1 Oct 2019
Approved by	State Health Executive	Secretary		3 Mar 2020

12. Revision History

Version	Approved by name	Approved by title	Amendment notes

Appendix 1 – Additional Roles and Responsibilities/Delegations

Governing / Peak Body (or equivalent) is responsible for:

- Providing executive leadership for the delivery of human research within the public health system and championing an integrated and whole of agency approach.
- Establishing the strategic direction and priorities and for the provision human research that meets the public health system and community needs, ensuring these are communicated effectively to the workforce and community.
- Ensuring the *Research Governance Policy Framework* (*RGPF*) is implemented and there are appropriate governance and management practices for the responsible conduct of human research.
- Ensuring there is an implementation framework for the *National Clinical Trials Governance Framework* (*NCTGF*), and research activities are of a high-quality and are delivered in a safe environment.
- Ensuring there is a partnering with patients, carers and consumers in the provision of human research.
- Ensuring there are structures and processes to monitor research activities and there are clearly well-defined communication systems and terms for reference for the timely exchange of information.
- Determining the level of resourcing and ensuring there are adequate resources and infrastructure with an adequate and an appropriately skilled workforce to conduct research.
- Ensuring the workforce have access to continuing professional development, education and training to develop a workforce skilled in the conduct of safe and high-quality responsible research practice.
- Ensuring ICT infrastructure is implemented to manage human research activities.
- Fostering the development of intellectual property and translation of research into evidence-based clinical practice.
- Monitoring safety and quality performance measures; overall research activity including revenue and expenditure in the provision of human research.
- Providing advice to the Secretary, as Head of Agency.

Department of Health (DoH) is responsible for:

- Establishing the policy framework that provides an integrated whole of agency approach for the responsible conduct of human research within the public health system.
- Providing policy education to the public health service workforce to ensure awareness for the effective implementation of this policy directive and broader strategic national reforms.
- Establishing a human research strategy that meets the public health system and the community needs.
- Promoting consumer-centred research and active consumer involvement in research planning and research activities.
- Implementation of an ICT system to manage human research activities.
- Providing continuous professional development and training opportunities to develop a workforce skilled in good clinical practice, safe and high-quality and responsible research practices.
- Monitoring human research activities to meet mandatory national reporting requirements and compliance with this policy directive.
- Monitoring the public health services implementation of *RGPF* and *NCTGF* and performance against agreed safety and quality measures.
- Providing advice on indemnity and insurance coverage for research projects and indemnity and insurance (where applicable).
- Providing advice on intellectual property, negotiation and settlement of issues about authorship, publication and potential commercialisation of projects (where applicable).
- Providing advice on contracts and research agreements for externally sponsored research projects (where applicable).
- Providing advice to the Governing / Peak Body and/or Secretary, as Head of Agency as required.

Chief Executive (CE) / Chief Operating Officer (COO) is responsible for:

- Establishing an implementation framework for the *RGPF* and *NCTGF* to ensure research activities are high-quality and are delivered in a safe environment with an integrated whole of agency approach.
- Ensuring adequate resources and structures are in place to meet the requirements of this policy directive for the effective governance of research.
- Ensuring there is an established Research Governance Office and Research Governance Officer (*RGO*) to provide process site authorisation applications for research projects within the public health service.

- Providing formal written site authorisation (or ensure delegation for research authorisation is document) for the commencement of a research project at the public health service.
- Establishing an implementation framework for a human research strategy.
- Promoting consumer-centred research by supporting and enabling active consumer involvement.
- Ensuring research personnel access continuous professional development, education and training to conduct safe and high-quality responsible research practice and there is appropriate supervision for Student / Trainee researchers.
- Ensuring systems (e.g. Data Safety Monitoring Board) are established to monitor the progress of research activities (where applicable).
- Ensuring the safe and secure storage and management of research data, records and primary materials.
- Monitoring of research activities, allegations of misconduct, complaints, adverse/safety events and expenditure and budget.
- Ensuring systems are in place for the management of allegations of misconduct, complaints and adverse/safety events.
- Fostering the development of intellectual property and translation of research into evidence-based clinical practice.
- Ensuring effective communication and terms of reference, including performance monitoring measures across the public health service with key individuals responsible for research.
- Providing advice to the Governing / Peak Body and/or Secretary, as Head of Agency as required.

Executive Directors (ED) / Directors (or equivalent) is responsible for:

- Ensuring staff are aware of responsibilities as outlined in the *RGPF* and *NCTGF* and research activities conducted at the public health service site are monitored for compliance.
- Ensure the *NCTGF* is assigned to an appropriate delegate/department for implementation and monitoring.
- Ensuring safe and high-quality research practice and supporting the responsible conduct of research.
- Ensuring proposed research activities align to institutional and/or departmental strategic plans and there are adequate resources and structures for research to be conducted.
- Ensuring compliance with the delegation for research approvals and site authorisation.
- Ensuring research personnel have the appropriate qualifications, authorisation to practice and experience to conduct research.
- Ensuring research personnel undertake continuous professional development, education and training, and Student/Trainee Investigators are appropriately supervised.
- Ensuring a supportive culture of responsible research practice across hospitals and/or services within their organisational structure.
- Ensuring systems (e.g. Data Safety Monitoring Board) are in place to monitor research activities and make recommendations on whether to continue, modify or stop the research for safety or ethical reasons.
- Ensuring compliance with safe and secure storage and management of research activity data, records and primary materials and, where possible and appropriate, facilitate access for study personnel.
- Ensuring reports of allegations of misconduct, complaints and adverse/safety events are appropriately investigated and systems to improve the conduct and governance of research are implemented.
- Conducting self-audit on compliance with good research practice guidelines.
- Promoting the development of intellectual property and the translation of research into evidence-based clinical practice.
- Ensure mechanisms are in place to collect and report on performance measures as required.
- Providing advice to the CE/COO, DoH or Governing / Peak Body and/or Secretary, as Head of Agency as required.

Research Director (and/or Manager) is responsible for:

- Promoting a of culture of responsible research practice and safe and high-quality research through the promotion and awareness of the *National Statement, The Code*, *RGPF* and *NCTGF*.
- Promoting the quality of research and the reputation of the public health service and its researchers by supporting and promoting the publication and dissemination of research findings within the public health services and to the wider public.

- Promoting peer review opportunities.
- Promoting the development of intellectual property and translation of research into evidence-based clinical practice.
- Promoting consumer-centred research by supporting and enabling active consumer involvement in planning activities and proposed research projects are relevant to the community needs.
- Promoting collaboration within the public health service and between institutions ensuring compliance with the both the public health service polices and the external intuition policies and guidelines.
- Promoting the mentoring of Student/Trainee Investigators and develop a positive research culture of safety and high-quality, excellence, integrity, professionalism and mutual respect.
- Monitor research activity, including reports of allegations of misconduct, complaints and adverse/safety events and participating in any inquiries conducted by the institution and the development of systems to improve the conduct and governance of research.
- Preparing the public health service annual research report.
- Providing advice to the CE/COO, DoH or Governing / Peak Body and/or Secretary, as Head of Agency as required.

Research Governance Officer (RGO) (or equivalent) is responsible for:

- Establishing effective and efficient processing of the governance review processes within the public health service in accordance with relevant guidelines, regulations, and legislation.
- Receiving and reviewing site specific assessment forms and supporting documents to complete the governance review.
- Providing advice on research governance matters to a range of parties including research personnel, Sponsors, institution Executives, Heads of Department/Divisional Directors and other parties seeking to undertake research within the public health service in accordance with national and local policies, guidelines and other reference material adopted by the jurisdiction.
- Monitoring regulatory and policy developments to ensure changes are incorporated into local policies and procedures in a timely manner.
- Monitoring research activity within the public health service/trial site and collecting and providing data to report on operational and performance metrics as required and the provision of data for the annual research report.

Pre-authorisation activities including:

- Liaising with relevant personnel regarding the preparation of the application for site specific assessment.
- Managing the process of site authorisation, reviewing the SSA form and recommending authorisation of the research project to the CE/COO (or delegate).
- Identification of potential risks of the proposed research activities to the institution.
- Selection of the appropriate risk management strategy to manage risks, including consideration of risk transfer or sharing (e.g. appropriate insurance coverage).
- Review and negotiate contracts, in consultation with relevant specialists as required, including, but not limited to, clinical research agreements, confidentiality agreements and those relating to conditions of employment for investigators.
- Ensuring collection of appropriate fees for site authorisation/governance review are invoiced to the external sponsor as required.
- Advising the authorising officer about the strategic fit of a proposed research project for their institution.
- Documenting all site-specific assessment decisions and maintaining records, including databases and filing systems.

Post-authorisation activities include:

- Reviewing and managing amendment documentation related to authorised research project.
- Monitoring authorised research projects through review of safety, annual progress and final reports.
- Receiving allegations of misconduct, complaints and adverse/safety events related to the conduct of a research project and escalating these to the appropriate officer in accordance with institutional policy and processes
- Conducting or co-ordinating audits of research projects on compliance with good research practice guidelines where required.

Project Closure activities include:

- Ensuring that the project closure process is orderly and systematic.
- Ensuring the public health service and its researchers are acknowledged for their contribution to the research activity and the reputation of the public health is safe-guarded.
- Ensuring the data and materials are appropriately managed in accordance with a research agreement and institutional policy.

Heads of Department/Division/Supporting Departments is responsible for:

- Ensuring responsible and safe and high-quality research practice, supporting investigators to undertake research and translating evidence-based research into clinical practice.
- Discussing the research project with the CPI (single-centre)/PI (multi-centre) and identifying potential risks and implementing risk management strategies and whether the project can meet the governance requirements.
- Ensuring alignment of the research project to institutional and/or departmental strategic plans and priorities.
- Ensuring there has been a feasibility assessment to determine the suitability of the site for the project (i.e. access to adequate pool of participants).
- Ensuring the institution has the appropriate facilities and infrastructure to conduct the research.
- Ensuring additional Support Services required have provided a quotation and services can be provided.
- Ensuring that the CPI/PI and associated investigators are appropriately credentialed, have the appropriate qualifications and/or training to conduct the research safely within their scope of practice.
- Ensuring any conflicts of interests of interest have been identified and are managed appropriately.
- Ensuring research personnel undertake continuous professional development, education and training and Student/Trainee Investigators are appropriately supervised.
- Ensuring that the revenue generated from commercially sponsored trials is used within the scope of this policy, ensuring accountability and transparency and efficient use of the funds.
- Ensuring funding sources and costs of the research project have been identified in the financial analysis and on the SSA form and project costs can be met by the Sponsor or if there is a shortfall, costs can be met by the Division/Department/Health Service.
- Ensuring cost centres are created (as required) to manage research funds and revenue generated from commercially sponsored trials is held within a designated cost centre.
- Monitoring and reporting of expenditure and budget for all research activities and provide reports as required on revenue expenditure.
- Ensuring research projects include a monitoring and audit plan to monitor the research project.
- Ensuring that all research projects within the Division/Department/Health Service have a CPI/PI.
- Ensuring reports of allegations of misconduct, complaints and adverse/safety events are appropriately investigations and systems to improve the conduct and governance of research are implemented.
- Conducting self-audit on compliance with good research practice guidelines.
- Providing advice to the CE/COO, RD, ED, Director/GM as required.

Business Manager (BM) is responsible for:

- Assisting the CPI (single-centre)/PI (multi-centre) in costing the conduct of the project in accordance with relevant staffing awards and guidelines, e.g. the Independent Hospital Pricing Authority (*IHPA*) and Medicare Benefits Scheme (*MBS*) or other industry guidelines.
- Ensuring additional Support Services required have provided a quotation and services can be provided.
- Determining cost recovery mechanisms (if applicable) for external and internal and service providers.
- Reviewing the budget in preparation for final sign off by an appropriate authority (e.g. Head of Department/Division and/or delegate).
- Ensuring funding sources and costs of the research project have been identified.
- Ensuring cost centres are created (as required) to manage research funds.
- Ensuring revenue generated from commercially sponsored trials is held within a designated cost centre and providing reports as required on any revenue expenditure.
- Providing financial reports on research expenditure and budget.

Coordinating Principal Investigator (CPI)/Principal Investigator (PI) is responsible for:

- The overall conduct, management and reporting of the project at a public health service site. (For single-centre trial the CPI/PI roles are generally synonymous. For multi-centre the PI is responsible).

- Ensuring the suitability of the public health service site (i.e. access to adequate pool of participants) and alignment of the project to institutional and/or departmental strategic plans.
- Liaising with the relevant personnel and support services to complete the financial analysis and SSA form that recognises the project costs and funding sources.
- Providing relevant information to the RGO (or equivalent body or individual) in a timely manner (i.e. in parallel to ethical review process) to enable the public health service to begin the site assessment process (where appropriate).
- Ensuring the provision of a contract/research agreement is where applicable and contractual requirements such as those under a research agreement are met.
- Ensuring and actual, potential or perceived conflicts of interest are disclosed and managed.
- Ensuring engagement with Aboriginal and Torres Strait Islander peoples and respecting their legal rights and local laws, customs and protocols (where appropriate).
- Ensuring that appropriate approvals are obtained prior to the commencement of the project, and that conditions of any approvals are adhered to during the project conduct.
- Ensuring the provision of participant information relates specifically to the institution.
- Informing the participant's primary physician about the participant's involvement in the project. if the participant has a primary physician and if the participant agrees to the primary physician being informed.
- Ensuring the welfare and any necessary clinical care is provided to research participants as a result of any adverse events experienced during or following the research project.
- Retaining the participant in a research project. Although a participant is not obliged to give his/her reason(s) for withdrawing prematurely from a study, the CPI/PI should make a reasonable effort to ascertain the reason(s), whilst fully respecting the participant's rights to withdraw.
- Taking responsibility for site investigators and supervising and mentoring Student/Trainee Investigators.
- Ensuring the CPI is notified of the research commencement (where appropriate).
- Providing information to the CPI to report to the HREC as required.
- Complying with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions per the approved research protocol.
- Retaining clear, accurate, secure and complete records of research activity including project data and primary materials. As appropriate, allow access and reference to these by the regulator and interested parties.
- Providing annual/final reports and reporting adverse/safety events to the institution and CPI (multi-centre).
- Provide the approving HREC (via the CPI if required) with a regular report on routine monitoring including concerns or issues arising from local audit.
- Advising the institution of any HREC outcomes/changes.
- Reporting suspected breaches of the Code to the relevant institution and/or authority. Providing any necessary documentation in the event of an investigation of research misconduct and complaints.
- Participating in peer review in a way that is fair, rigorous and timely and maintains the confidentiality of the content
- Ensuring the acknowledgement of those who have contributed to the research activity and citation of other relevant work is appropriate and accurate, ensuring that authors are those who have made a significant intellectual or scholarly contribution, and that they agree to be listed as an author.
- Disseminating research project findings responsibly, accurately and broadly e.g. participants, funding bodies and other stakeholders. Where necessary, act to correct the record in a timely manner.
- Completing and maintaining approved Good Clinical Practice (GCP) certification.
- Maintain current CV in an institution database, including professional registrations.
- Maintain professional indemnity insurance (where applicable).
- Compliance with public health service record storage policies (including future destruction).
- Following up on intellectual property and commercialisation activities (where applicable).

Associate Investigator(s) is responsible for:

- Assisting the CPI (single-centre)/PI (multi-centre) in completing ethics and governance documents as delegate, liaising with relevant personnel and support services (where applicable).
- Conducting research projects in accordance with the agreed protocol, legal, regulatory and institutional requirements.

- Where relevant (e.g. some clinical trials), provide clinical interventions/treatments as per the protocol and scope of practice; or collect data as required, within their study delegation.
- Retaining accurate, secure and complete records of all research activities including data and primary materials.
- Complying with institutional policies on governance (such as Good Clinical Practice guidelines) and other requirements regarding research projects.
- Liaising with the CPI/PI and Sponsor regarding the management, monitoring of the research project.
- Ensuring participants' safety and welfare during the research project and reporting safety/adverse events.
- Completing and maintaining approved Good Clinical Practice (GCP) certification.
- Maintain current CV in an institution database, including professional registrations.
- Maintain professional indemnity insurance (where applicable).

Clinical Research Coordinator (CRC)/ Clinical Trail Nurse CTN /Research Assistant (or equivalent) is responsible for:

- Assisting the CPI (single-centre)/PI (multi-centre) in completing ethics and governance documents as delegate, liaising with relevant personnel and support services (where applicable).
- Conducting research projects in accordance with the agreed protocol, legal, regulatory and institutional requirements.
- Where relevant (e.g. some clinical trials), provide clinical interventions/treatments as per the protocol and scope of practice; or collect data as required, within their study delegation.
- Retaining accurate, secure and complete records of all research activities including data and primary materials. As appropriate, allow access and reference to these by the regulator and/or interested parties.
- Complying with institutional policies on governance (such as Good Clinical Practice guidelines) and other requirements regarding research projects.
- Liaising with the CPI/PI, Sponsor, RGO and BM regarding the management, monitoring and financial reporting of the research project.
- Ensuring participants' safety and welfare during the research project and reporting safety/adverse events.
- Completing and maintaining approved Good Clinical Practice (GCP) certification.
- Maintain current CV in an institution database, including professional registrations.

Human Research Ethics Committee (HREC) and Scientific sub-committee is responsible for:

- Reviewing the human research proposal to form a view on its ethical acceptability (in accordance with the National Statement).
- Providing the CPI (single-centre)/PI (multi-centre), with the outcome of the ethical review of the human research project.
- Providing advice and receive reports from institutions regarding complaints or reports of research misconduct arising out of the conduct of approved human research.
- Monitoring research for which it has given approval, through the receipt of safety, progress and any other required reports in conjunction with the participating institutions and their research governance offices.
- Publishing the Terms of Reference including membership, meeting dates and submission deadlines.

Ethics Executive Officer (EEO) is responsible for:

- Providing administrative support and advice on the Human Research Ethics Committee (HREC), its subcommittees for the ethical review of research projects.
- Providing expert advice to investigators seeking to undertake research in accordance with relevant policies.
- Providing secretariat support for a HREC (and sub-committees if applicable); document HREC decisions and maintain a current record on research activities.
- Providing ongoing monitoring of research activities, including managing amendments, adverse events, annual progress and final reports, managing appeals and notification of complaints, misconduct and conflicts of interest.
- Preparing the annual reporting of HREC activity to the NHMRC.

ICT System/Database Administrator is responsible for:

- Administering the ICT System/Database used for the management of research activities.
- Providing face-to-face training and/or desktop support for new ICT users, staff and researchers.
- Support development or release of reports from ICT systems as required to monitor and report on research activity.
- Participate in any ICT Business User Groups to evaluate and approve system enhancements.
- This role may be delegated to the RGO at the public health service.

Student Investigator/Research Trainees is responsible for:

- Undertaking required induction and training in responsible research conduct
- Where the Student/Trainee, is listed as a Site Investigator, assist the CPI (single-centre)/PI (multi-centre) as delegated; and ensure a Supervisor is identified.
- Where the Student/Trainee, is listed as the Principal Investigator, conduct the research in accordance with the public health service policies and guidelines; and ensure there is appropriate Supervisor.

Student/Trainee Supervisor is responsible for:

- Ensuring oversight of all Student/Trainee research activities at the public health service site.
- Where the Student/Trainee, is listed as a Site Investigator, provide a supervisory role and act as a primary source of guidance to the student and point of contact for the CPI/PI for any student matters.
- Where the Student/Trainee, is listed as a Principal Investigator, provide advice on applicable public health service policies and guidelines; ensure ethics and governance documents are of a high standard and the conduct the research in accordance with the public health service policies and guidelines.

Data Custodian is responsible for:

- Responsible officer regarding "ownership" of the service specific data.
- Data integrity and data validation and interpretation.
- Supporting the overall strategic position for data re-use.
- Authorising access/release of the data in accordance with institution policy, legislation, privacy and other guidelines.

Data Steward is responsible for:

- Data entry and data quality.
- Providing information to investigators on datasets available to assist in the feasibility assessment for research activities requiring data requests.

Trial Sponsor is responsible for:

- The trial 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.
- Where the public health service is the trial Sponsor (e.g. investigator-initiated/collaborative group) the institutions governing body is the Sponsor and ensures that its overarching governance and quality management systems delineate its responsibilities as a trial sponsor from its responsibilities as a trial site and ensures that the requirements of Sponsorship can be met.
- Submitting a CTN or CTX to the TGA if required.
- Ensure the importance and relevance of the research question and validity of the proposed setting and methodology has been assessed through scientific/peer review, and the trial team and trial sites are suitable.
- Encouraging CPI (single-centre)/PI (multi-centre) to discuss their proposed trials with ethics and/or governance staff at an early stage, to identify any issues or risks.
- Promote consumer-centred research by supporting and enabling active consumer involvement.
- Ensuring agreements with third parties consider any funding, indemnities, insurances, confidential information, intellectual property, ownership and authorship related to the research projects.
- Ensuring that any Sponsor functions that are delegated to CPI (single-centre)/PI (multi-centre) (or other third parties), are clearly documented and understood.
- Disclose and manage actual, potential or perceived conflicts of interest.
- Ensure there is a documented monitoring and audit plan and documented process to receive adverse/safety event reports.
- Report suspected breaches of the Code to the relevant institution and/or authority.

- Disseminate research activity findings responsibly, accurately and broadly. Where necessary, take action to correct the record in a timely manner investigator who have contributed to the research project, and cite and acknowledge other relevant work appropriately and accurately.
- Where the public health service is the trial Sponsor:
- Establishing a process to assess each investigator-led/collaborative group research project to determine whether the project is consistent with the institution's research priorities and risk tolerance level before agreeing to act as Sponsor (e.g. assessment of the trial by a research governance committee).
- Ensure that CPI (single-centre)/PI (multi-centre) have access, where appropriate, to support, expertise and tools relating to research activities delegated to them (e.g. support to develop grant applications, protocols, safety monitoring plans, randomisation and blinding systems and data management and analysis plans).

Participants and Consumers, where applicable, are responsible for:

- Providing feedback, complaints and compliments about experiences in the public health service, including participating in 'patient experience' surveys.
- Communicating about potential safety and quality risks and opportunities for improving the conduct of research activity at the public health service.
- Participating in the review of safety and quality incidents or other serious adverse events relating to the conduct of research activities.
- Advocating and/or representing patients and participants involved in research activities, in focus groups and meetings to improve participation in research.
- Sharing experiences through patient stories, information sessions, letters, pictures, patient journeys, or presentations at meetings or training sessions for the workforce.
- Planning and sharing decisions about participation in research; asking for more information about involvement in research, and requesting information in different formats or a translator, if required.
- Advising the public health service workforce who should be involved in sharing decisions about their participation in a research.
- Participating in the governance of research within the public health service, when opportunities exist.
- Participating in the development and review of health information for consumers about research.

Appendix 2 - Glossary and Definitions

Glossary

ACSQHC	Australian Commission on Safety and Quality in Healthcare
AHMAC	Australian Health Ministers' Advisory Council
AIHW	Australian Institute of Health and Welfare
ANZCTR	Australian New Zealand Clinical Trials Registry
AT	Ambulance Tasmania
APHCRI	Australian Primary Health Care Research Institute
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CHaPS	Child Health and Parenting Services
CHC	Community Health Centre
COAG	Council of Australian Governments
COO	Chief Operating Officer
DH	District Hospital
DoH	Department of Health
DON	Director of Nursing
GST	Goods and Services Tax
HACC	Home and Community Care
HoMER	Harmonisation of Multi-Centre Ethical Review
ICC	Integrated Care Centre
ICU	Intensive Care Unit
IHPA	Independent Hospital Pricing Authority
KPI	Key Performance Indicator
LGH	Launceston General Hospital
MCH	Mersey Community Hospital
MBS	Medicare Benefits Schedule
MPC	Multipurpose Centre
MPS	Multipurpose Service
NHMRC	National Health and Medical Research Council
NICS	Northern Integrated Care Service
NSQHSS	National Safety and Quality Health Service Standards
OHST	Oral Health Services Tasmania
NWRH	North West Regional Hospital
QI / QA	Quality Improvement / Quality Assurance
RHH	Royal Hobart Hospital
RTI	Right to Information
SMHS	Statewide Mental Health Services
THS	Tasmanian Health Service (THS)
TI	Treasurer's Instruction
TRMF	Tasmanian Risk Management Fund
UTAS	University of Tasmania
WACS	Women's and Children's Services
WCDH	West Coast District Hospital

Definitions

Aboriginal	The use of the term "Aboriginal" within this document refers to both Aboriginal and Torres Strait Islander people.
Adverse Event/Safety Event	Any undesirable clinical occurrence in a subject, whether it is considered to be device related or not, that includes a clinical sign, symptom or condition and/or observation of any unintended technical performance or performance outcome of the device. An adverse event includes: • serious adverse event • serious adverse device event • suspected unexpected serious adverse reaction • unanticipated serious adverse device event • protocol deviation or violation
Amendment	A written description of a change(s) to or formal clarification of a protocol or the research project. An amendment may be: • Minor Amendment • Substantial Amendment
Australian Business Number (ABN)	An Australian Business Number (ABN) is a unique file number assigned by the Australian Securities Investments Commission (ASIC) to an individual or organisation conducting an enterprise for business tax purposes.
Australian Health Ethics Committee (AHEC)	The committee that advises the National Health and Medical Research Council (NHMRC) on ethical issues related to health.
Australian New Zealand Clinical Trials Registry (ANZCTR)	An online publicly available register of clinical trials being undertaken in Australia, New Zealand and elsewhere. The ANZCTR includes trials from the full spectrum of therapeutic areas of pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies.
Australian Health Practitioner Regulation Agency (APHRA)	The Australian Health Practitioner Regulation Agency (AHPRA), established by section 23(1) of the National Law. AHPRA works in partnership with the National Boards to establish the National Scheme to regulate the National Registration and Accreditation Scheme for registered health practitioners.
Certified HREC	An institution that has undergone assessment against criterion contained in the National Certification Scheme and has been certified under the NHMRC National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-Centre Research to provide National Mutual Acceptance (NMA).
Clinical Interventional Research (other than clinical trials)	Interventional research involving human participants in health and illness done in response to a clinical research question. The aim of such research is to inform clinical practice through the application of patho-physiological, population-based, behavioural or qualitative research methods.
Clinical Quality Registry	Clinical quality registries are organisations which systematically monitor the quality (appropriateness and effectiveness) of healthcare, within specific clinical domains, by routinely collecting, analysing and reporting health-related information. Clinical quality registries are a specific type of clinical registry. They use the data they collect to identify benchmarks and variation in clinical outcomes. They then feed this information back to clinicians to inform clinical practice and decision making. This clinical outcome feedback loop is the defining feature of clinical quality registries.
Clinical Trial	A research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial is the name commonly given to research in which a therapeutic, preventive or diagnostic intervention is tested in a systematic way. The terms 'clinical trial' and 'clinical research' are sometimes used interchangeably. The intervention type may be: • Drug Clinical trials • Surgery and other procedural interventions • Devices • Other: Studies that do not fall under the broad definitions of drug, surgical, or device trials. Examples include interventions such as exercise, physiotherapy, cognitive therapy, special diets, herbal medicines, web-based treatments, motivational classes, music therapy, and stem cell interventions.
Clinical Trial Exemption (CTX)/ Clinical Trial Notification (CTN)	A clinical trial involving medicines, biologicals and/or medical devices is conducted under the Clinical Trial Notification or Clinical Trial Exemption Schemes.

Clinical Trial Phase	Many clinical trials to develop new interventions are conducted in phases. In the early phases, the new intervention is tested in a small number of participants to assess safety and effectiveness. If the intervention is promising, it may move to later phases of testing where the number of participants is increased to collect more information on effectiveness and possible side effects. Clinical trials of biomedical interventions typically proceed through four phases (Phase I, II, III, IV). See also Exploratory studies.
Clinical Trial Research Agreement (CTRA)	A legally binding written agreement between two or more parties, which sets out the responsibilities and obligations of each party. The type of research agreement used is determined by the nature of the research project as outlined in the Protocol.
Collaborative or Cooperative Research Group (CRO)	Is an academic and/or non-commercial collaborative research group responsible for sponsoring, initiating, managing, developing and coordinating the Study. See also non-commercial clinical trial.
Commercially Sponsored Clinical Trial	A clinical trial where the Sponsor or Contract Research Organisation (CRO) is a company or organisation that takes responsibility for the initiation, management, indemnity and financing of a clinical trial and endorses the CTN or CTX form. The project protocol has been developed by the commercial entity, and it retains ownership of the product, project material and intellectual property. Consequently, the risks and liabilities associated with the trial are borne primarily by the sponsor/CRO and they must provide indemnity and insurance.
Contract Research Organisation (CRO)	A person or organisation (commercial, academic or other) contracted by a Sponsor to perform one or more of a sponsor's trial-related duties or functions.
Coordinating Principal Investigator (CPI)	the PI who has designed the clinical trial and who takes overall responsibility for it. CPIs may also be referred to as Lead Principal Investigator and Chief Principal Investigator.
Cost Centre	A financial reporting code specific to a Health Entity.
Data Safety Monitoring Board (DSMB)	A multidisciplinary group established by the trial sponsor to review, at regular intervals, accumulating trial data, in order to monitor the progress of a clinical trial. Their role is to provide advice on safety and/or trial conduct issues by making recommendations to the sponsor, or the Trial Steering Committee (TSC), on whether to continue, modify or stop a trial for safety or ethical reasons. DSMBs may also be referred to as Data Monitoring Committee (DMC) and Data Monitoring and Ethics Committee (DMEC).
Department of Health Legal Services	Responsible for the provision of legal advice on a range of matters, including commercial and contracts management and indemnity.
Donor	An individual or organisation donating to the Health Entity. The donation may include money, goods and/or services.
Ethical review	The review of research by an HREC or other body.
Ethical approval	A determination by an ethical review body that a research project satisfies ethical standards and requirements, of the NHMRC, National Statement on Ethical Conduct in Human Research 2007 (National Statement).
Evaluation	The systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity. The term is used in a broad sense to refer to any set of procedures, activities, resources, policies and/or strategies designed to achieve some common goal or objective.
Exploratory studies	Sometimes referred to as 'Phase 0 trials' or 'pilot studies'. These come before Phase I trials and are used to test how the body responds to an experimental drug. In these studies, small doses of the new drug are given once or for a short time to a very limited number of people.
Feasibility Assessment	A process to determine whether a trial site has the capacity and capability, including resources, expertise and participant pool to carry out a specific clinical trial.
First Participant Recruitment	Start date = the first point of recruitment i.e. the date when the advertising or screening for participants begins. Also known as site activation.
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected.
Grants	Funds provided for a single discrete specified purpose and period and not constituting the entire financial base of an organisation.
Human Research Ethics Application Form (HREA)	The HREA is a national, web-based application form for investigators of all disciplines to complete research ethics proposals for submission to HRECs.

Human Research Ethics Committee (HREC)	An institution that has established an ethical review body in accordance with NHMRC, National Statement on Ethical Conduct in Human Research 2007 (National Statement) to conduct the scientific and ethical review of research. Internationally, HRECs may be referred to as an Institutional Review Board (IRB) and Institutional Ethics Committee (IEC).
Institution (site)	Any public or private entity or medical facility where research is conducted.
Intellectual Property (IP)	Is an intangible business asset, such as an invention, trade mark, design, brand or even the application of a new idea. It is important to manage the ownership and use of all types of IP when negotiating a clinical trial research agreement (CTRA).
Investigator's brochure	compilation of clinical and non-clinical data on the investigational product(s) relevant to the study of investigational product(s) in human subjects.
Investigational Product	Is the medicine or device being trialled or tested in the project and includes where relevant any placebo.
Low risk research	where the only foreseeable risk to the participant is one of discomfort. Discomforts may include minor side-effects of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.
Medicines Australia (MA)	The national association that represents the pharmaceutical companies that invent, manufacture and supply innovative medicines and vaccines in Australia.
Medical Technology Association of Australia (MTAA)	The national association representing medical technology companies in the medical technology industry in Australia.
Monitoring	The act of overseeing the progress of a research project, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirement(s).
Multi-Centre Research	Research that is conducted at more than one site within the public health system.
National Mutual Acceptance (NMA)	The system of single scientific and ethical review of multi-centre human research projects across Australian jurisdictions (public health organisations only) whereby one certified HREC provides the ethical review for a research proposal that is accepted by the other institutions participating in the multi-centre research.
Negligible risk research	No foreseeable risk of harm or discomfort and any foreseeable risk is not more than inconvenience to the participants. Inconvenience is the least form of harm that is possible for human participants in research. The most common examples of inconvenience in human research are filling in a form, participating in a survey or giving up time to participate in a research activity. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.
Non-Commercial Clinical Trial	An investigator-initiated trial which can be unsponsored, sponsored, involve grants or be part of a collaborative research group.
Non-HREC level alternative	A person or body (e.g. subcommittee or delegate) that conducts an ethical review of a research project which is an alternative to that of a full HREC.
Office of the Crown Solicitor (OCS)	The Office of the Crown Solicitor provides commercial law and conveyancing services to the Government.
Participant Information and Consent Form (PICF)	The form providing the reason the participant is being invited to take part in the research project and to explain the purpose and involvement of the study with the inclusion to sign the form indicating consent to participate in the trial.
Project Reference Number (PRN)	The unique project number allocated to a research project to identify research projects.
Protocol	A document that provides the background, rationale and objectives of the research project and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.
Quality Improvement (QI)/ Quality Assurance (QA)	An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA activity. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably.
Research	"Original investigation undertaken to gain knowledge, understanding and insight" (*Australian Code for the Responsible Conduct for Research, 2007*).

Research Governance	A process used by an organisation for the oversight, assessment, authorisation and monitoring of research conducted at one or more of its sites or under its auspices. A research governance framework includes good research culture and practice, organisational strategy, role definition and accountabilities, risk, resource and financial assessment and management, compliance with legal, regulatory and contractual requirements, competencies and training of personnel, site assessment, scientific review, ethical review and approval, site authorisation, monitoring of research, and management of conflicts of interest, complaints and allegations of research misconduct.
Single-Centre Trial	Research that is conducted at one site only within the public health system (i.e. single-site research).
Single Ethical Review	A process whereby one certified HREC provides the ethical review for a research proposal that is accepted by the other institutions participating in the multi-centre research. See also NMA.
Site (institution)	Any public or private entity or medical facility where research is conducted.
Site Assessment	A process that assesses research against institutional requirements and any applicable jurisdictional requirements (including legal obligations). The outcome of a site-specific assessment is site authorisation: a determination by an organisation that a research project to be conducted at one or more of its sites or under its auspices satisfies organisational requirements and may commence at the site/s over which it exercises its authority.
Site Authorisation	A determination by an organisation that a research project to be conducted at one or more of its sites or under its auspices satisfies organisational requirements and may commence at the site/s over which it exercises its authority. Site authorisation is the outcome of the site-specific assessment process.
Site-Specific Assessment (SSA)	A mechanism used by the Health Service to ensure that the proposed research project complies with governance requirements, and to consider whether the research should be conducted and supported at the proposed site.
Site staff	All staff involved in a trial at the site.
Sponsor	An individual, company, institution or organisation that takes responsibility for the initiation, management and/or financing of research. Sponsors can be commercial companies, collaborative research groups, government entities including health service organisations, individual investigators, or universities.
Supporting Departments	Departments within the institution/site that are not specifically conducting the research project but will be providing services to support the research project (e.g. pharmacy, pathology, medical records and imaging).
Tasmanian Risk Management Fund (TRMF)	The whole-of-government self-insurance arrangement for funding and managing specific identified insurable liabilities of participants. TRMF is administered by the Department of Treasury and Finance. Claims administration is undertaken by a contracted Fund Administration Agent, Jardine Lloyd Thompson Pty Ltd.

Tasmania Health Service(s) (THS)	The Tasmanian Health Service Act commenced on 1 July 2018. The THS incorporates:
	• Royal Hobart Hospital
	• Launceston General Hospital
	• North West Regional Hospital
	• Mersey Community Hospital
	• District Hospital Services/Multi-Purpose Services/ Multi-Purpose Services Centres
	• Primary Health Services
	• Services Delivery Centres:
	  o Statewide Mental Health Services
	  o Alcohol and Drug Services
	  o Correctional Primary Health Services
	  o Child and Community Health Centres and Services (CHaPS)
	  o Ambulance Tasmania (AT)
	  o Oral Health Services Tasmania (OHST)
	  o Public Health Services

Therapeutic Goods Administration (TGA)	The regulatory authority responsible for regulating the supply, import, export, manufacturing and advertising of medicines, medical devices, blood, and tissues.

Appendix 3 - Legislation Frameworks

State

The Tasmanian Legislation is the authorised public website that provides access to legislation currently in force in Tasmania.

1 Adoption Act 1988

2 Alcohol and Drug Dependency Act 1968

3 Ambulance Service Act 1982

4 Anatomical Examination Act 2006

5 Anti-Discrimination Act 1998

6 Archives Act 1983

7 Asbestos-Related Diseases (Occupational Exposure) Compensation Act 2011

8 Audit Act 2008

9 Blood Transfusion (Limitation of Liability) Act 1986

10 Births, Deaths and Marriages Registration Act 1999

11 Child Protection (International Measures) Act 2003

12 Children, Young Persons and Their Families Act 1997

13 Conveyancing and Law of Property Act 1884

14 Coroners Act 1995

15 Constitution (State Employees) Act 1994

16 Criminal Justice (Mental Impairment) Act 1999

17 Disability Discrimination Act 1992

18 Disability Services Act 1992

19 Fee Units Amendment Act 2002

20 Financial Management 2016

21 Fluoridation Act 1968

22 Guardianship and Administration Act 1995

23 Health Act 1997

24 Health Complaints Act 1995

25 Health Services Establishments Act 2006

26 Health Practitioner Regulation National Law (Tasmania) Act 2010

27 Human Cloning for Reproduction and Other Prohibited Practices Act 2003

28 Human Embryonic Research Regulation Act 2003

29 Human Tissue Act 1985

30 Industrial Relations Action 1984

31 Integrity Commission Act 2009

32 Medical Radiation Science Professionals Registration Act 2000

33 Mental Health Act 2013

34 Misuse of Drugs Act 2001

35 Motor Accidents (Liabilities and Compensation) Act 1973

36 Personal Information Protection Act 2004

37 Pharmacy Control Act 2001

38 Poisons Action 1971

39 Public Health Act 1997

40 Public Interest Disclosures Act 2002

41 Radiation Protection Act 2005

42 Right to Information Act 2009

43 State Services Act 2000

44 Surrogacy Contract Act 1993

45 Tasmanian Health Services Act 2018

46 Therapeutic Goods Act 2001

47 Workers Rehabilitation and Compensation Act 1988

48 Workplace Health and Safety Act 2012

49 Youth Justice Act 1997

Commonwealth

The Federal Register of Legislation is the authorised public website for Commonwealth legislation and related documents.

50 Aged Care Act 1997 (CTH)

51 Australian Radiation Protection and Nuclear Safety Act 1998 (CTH)

52 Australian Research Council Act 2001 (CTH)

53 Biosecurity Act 2015 (CTH)

54 Copyright Act 1968 (CTH)

55 Corporations Act 2001 (CTH)

56 Gene Technology Act 2000 (CTH)

57 Health Insurance Act 1973 (CTH)

58 Industry Research and Development Act 1986 (CTH)

59 National Health and Medical Research Council Act 1992 (CTH)

60 Privacy Act 1988 (CTH)

61 Research Involving Human Embryos Act 2002 (CTH)

62 Therapeutic Goods Act 1989 (CTH)

Safety and Quality Frameworks

63 Australian Commission on Safety and Quality in Health Care. National Model Clinical Governance Framework (2nd edition).

64 Australian Commission on Safety and Quality in Health Care (ACSQHC), (2019). National Clinical Trials Governance Framework.

65 Australian Commission on Safety and Quality in Health Care (ACSQHC, (2014). Framework for Australian clinical quality registries.

Appendix 4 – References, Documents and Policies

The following International, Commonwealth and State organisations provide frameworks, guidelines and policies that guide the governance of research.

International

1 Australian New Zealand Clinical Trials Registry (ANZCTR)

2 ClinicalTrials.gov

3 Consolidated Standards of Reporting Trials (CONSORT)

4 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

5 International Federation of Pharmaceutical Manufacturers & Associations

6 International Standard Randomised Controlled Trial Number (ISRCTN) Register

7 US Department of Health and Services Office for Human Research Protections

8 World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects

9 International Air Transport Association (IATA) Dangerous Goods Regulations (DGRs)

Commonwealth

10 Australian Business Number (ABN) Lookup

11 Australian Bureau of Statistics, Australian and New Zealand Standard Research Classification (ANZSRC), 2008

12 Australian Clinical Trials

13 Australian Department of Health & Ageing Gene Technology Regulator

14 Australian Electoral Commission, Supply of Elector Information for Use in Medical Research

15 Australian Federation of International Forwarders, IATA Publications

16 Australian Government Department of Health, Medicare Benefits Schedule (MBS) Book (MBS Schedule)

17 Australian Health Practitioner Regulation Agency

18 Australian Institute of Health and Welfare

19 Australian Prudential Regulation Authority (APRA)

20 Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)

21 Australian Red Cross Blood Service (ARCBS)

22 Australian Red Cross Blood Service documents, Receipt and Use of Blood Service Shippers by External Institutions to Transport Blood and Blood Products

23 Australian Research Council, (2017). National Principles of Intellectual Property Management for Publicly Funded Research

24 Australian Research Council. The Australian and New Zealand Standard Research Classification (ANZSRC)

25 Australian Securities and Investments Commission (ASIC)

26 Clinical Oncology Society of Australia (COSA), (2016). Australasian Tele-Trial Model

27 Independent Hospital Pricing Authority (IHPA). Determination of standard costs associated with conducting clinical trials in Australia Standard List of Clinical Trial Items June 2015

28 Independent Hospital Pricing Authority (IHPA). Development of a table of standard costs for conducting Clinical Trials in Australia 2015 Final Report

29 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH): ICH Harmonised Guideline - Integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) – Annotated with TGA Comments

30 Intellectual Property (IP) Australia

31 Medical Technology Association of Australia (MTAA), Clinical Investigation Research Agreement

32 Medical Technology Association of Australia (MTAA). Compensation Guidelines

33 Medicines Australia (MA) Clinical Trials

34 Medicines Australia (MA) Clinical Trial Research Agreements (CTRA)

35 Medicines Australia (MA) Indemnity & Compensation Guidelines

36 National Association of Testing Authorities (NATA)

37 National Blood Authority

38 National Health and Medical Research Council, (2018). Australian Code for Responsible Conduct of Research (The Code)

39 National Health and Medical Research Council) (2010). Biobanks Information Paper

40 National Health and Medical Research Council, (2018). Competencies for Australian Academic Clinical Trialists

41 National Health and Medical Research Council, (2018). Data Safety Monitoring Boards (DSMBs)

42 National Health and Medical Research Council, (2018). Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders

43 National Health and Medical Research Council, (201). Ethical Guidelines for organ transportation from deceased donors

44 National Health and Medical Research Council, (2017). Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research

45 National Health and Medical Research Council, (2012). Framework for Monitoring: Guidance for the National Approach to Single Ethical Review

46 National Health and Medical Research Council, (2016). Good Practice Process for Site Assessment and Authorisation Phases of Clinical Trial Research Governance

47 National Health and Medical Research Council, (2016). Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods

48 National Health and Medical Research Council, (2018). Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research

49 National Health and Medical Research Council, (2011). Insurance and indemnity for multi-centre research

50 National Health and Medical Research Council, National Certification Scheme Institutions with certified ethics review processes

51 National Health and Medical Research Council, National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) (National Statement)

52 National Health and Medical Research, (2016). Principles for Accessing and Using Publicly Funded Data for Health Research

53 National Health and Medical Research Council, (2018). Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods

54 National Health and Medical Research Council, (2011). Research Governance Handbook: Guidance for the national approach to single ethical review

55 National Health and Medical Research Council, (2018). Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods

56 National Health and Medical Research Council, Standardised participant information and consent forms (PICFs)

57 National Health and Medical Research Council, (2016). Statement on Consumer and Community Involvement in Health and Medical Research

58 National Pathology Accreditation Advisory Council (NPAAC), (2013). Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials

59 Population Health Research Network (PHRN)

60 Research Australia

61 Therapeutic Goods Administration (TGA)

Policy Frameworks

The Strategic Document Management System is the storage and management system for the Department of Health and Tasmanian Health Service strategic documents including policies and subordinate documents.

1 Access to Dental Records Oral Health Services Tasmania

2 Administrative Data Exchange Protocol for Tasmania (ADEPT)

3 Corporate Delegations and Administrative Authorities - Policy

4 Data Exchange Toolkit

5 Department of Health, Employment Obligations – Department – Policy

6 Department of Health, Employment Obligations – Worker – Policy

7 Disposal Schedule 20 (DS20) Patient and Medical Records

8 Financial Compliance - Policy

9 Financial Management Manual (FMM)

10 Guidelines for seeking Advice from the Solicitor-General's Office (TIs 11118)

11 Procedure for seeking Crown Law Advice - Procedure

12 PIP Act Manual

13 Public Sector Awards

14 Records and Information Management - Policy

15 THS Medical Records Management - Policy

16 THS Alerts Registration and Protocol

17 THS Consumer Engagement - Policy

18 THS Consumer Rights and Engagement - Policy

19 THS Release of Medical Records Protocol

20 Treasurer's Instructions (TIs)