Research Handbook

Research Governance Framework and Guidelines for Conducting Human Research at Epworth HealthCare

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1. Purpose

Epworth HealthCare (Epworth) is committed to delivering excellent clinical services and outcomes for patients that are informed by research and delivered in a regulated environment of continuous quality improvement. This requires a governance framework that encourages and supports clinical research.

Epworth is accountable for the quality, safety and ethical acceptability of research undertaken on its sites, by its staff and with its patients. Research conducted at Epworth must therefore be conducted in accordance with local, national and international ethical principles, guidelines for responsible research conduct, legislations and regulations. All researchers at Epworth must comply with *Australian Code for the Responsible Conduct of Research* (the Code), *National Statement on Ethical Conduct in Human Research* (National Statement), *National Clinical Trial Governance Framework*, *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods*, and the *International Council on Harmonisation (ICH) Guidance for Good Clinical Practice E6 (R2).* These regulations establish frameworks for responsible research conduct that provides a foundation for high-quality research, credibility and community trust in the research endeavour.

The purpose of this document is to set out the overarching requirements for conducting research at Epworth and to give guidance to both researchers and reviewers to ensure that research being undertaken is:

- Safe,
- Valid,
- High quality; and
- Fulfils all regulatory requirements

This document will be revised on a regular basis and is intended to be used as a reference document only. Please contact the Epworth Research Development and Governance Unit (RDGU) for any queries or suggestions for improvements at: research@epworth.org.au. Further contact details can be obtained here: https://www.epworth.org.au/working-with-us/research

2. Definition of Epworth Research

At least one of the following criteria must apply for a research project to be defined as Epworth Research:

- The research impacts directly or indirectly on Epworth patients - inpatients or outpatients
- Epworth is funding the research directly
- The project uses significant Epworth resources (including staff training and service delivery)
- The research could impact on Epworth's reputation

Research by VMOs with rooms on Epworth premises, either owned or leased, is not automatically defined as being Epworth research with RDGU oversight unless it meets one of the criteria above. Some research may occur entirely within the rooms of Epworth VMOs and may not involve Epworth in any of the ways defined above. In these cases Epworth does not need to be involved in the oversight of this research but this may be requested.

3. The Governance Framework at Epworth

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 Epworth whilst promoting and fostering a good research culture and practice. At an organisational level studies must be feasible, financially sustainable and delivered in a manner that minimises the impact on staff and participants routine clinical care.

At Epworth we have created processes to ensure that the ethical, legal, regulatory, strategic and logistical requirements are met through a streamlined governance process. A clinical research quality management system (rQMS) based on Transcelerate's clinical Quality Management System has been implemented to mitigate research risks, guide researchers, and enhance the overall quality and safety of clinical research conducted at Epworth. Elements of the rQMS include a Research Policy, Research Handbook, and a suite of Standard Operating Procedures (SOPs) which are accessible on the RDGU website. Researchers intending to conduct research at Epworth should first read these documents and associated regulatory guidelines to understand the requirements of conducting research at Epworth.

3.1. New Research Proposals and Endorsement

Epworth has an overarching strategy with which all researchers should be familiar before planning to undertake research at Epworth. It is important that all researchers understand the clinical service delivery model at Epworth to ensure that their proposed research is aligned with this and can be accommodated. To achieve this, we require all researchers to discuss their projects with the relevant people that will be involved in any way at all Epworth divisions. In practice this will mean that researchers should speak with any manager responsible for access to facilities, 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 RDGU will periodically assess whether the risk profiles of new research activities collectively impact the Epworth Research Risk Profile Chart, an internal and confidential tool for assessing the risk profile of research activities at Epworth against the organisation's risk appetite for research.

Researchers will require signed approval of their proposed research from the relevant manager and/or a member of the Epworth Executive (see Appendix A Governance Approval Hierarchy). We strongly encourage that these conversations about the risks and resource requirements to include all relevant stakeholders including the RDGU as early as possible as experience shows that failure to do so can result in delays or failure of the study at critical time points.

It is a mandatory requirement that all new research projects are registered with the RDGU at the time of site selection and before commencement. If there is any intention for Epworth to be a lead site over a multi-site study, researchers must discuss with the RDGU prior to listing Epworth as a lead site. This allows the RDGU to ensure that all relevant stakeholders have been included at this point and assist researchers to avoid problems that may otherwise arise. The RDGU can also assist in all aspects of the research to be conducted at Epworth including research development (protocol design, statistical assistance where required) through to achieving ethical and institutional approvals as outlined in Appendix A (elements of which are outlined in the following sections).

When registering projects, please provide the Research Governance Office with the following information:

- Study title
- Principal Investigator
- Sponsor or Source of Funding
- Study Coordinator
- Epworth site(s)
- Brief summary of the study or a copy of the project proposal or protocol
- NMA ethics committee or Institutional ethics committee approval status

Please refer to SOP-RG-01 Research Governance for guidance in preparing and submitting documentation for governance review.

To contact the RDGU please email: research@epworth.org.au or telephone (03) 9426 8630

3.2. Protocol Design

A high-quality and well thought out protocol will assist in smooth project implementation, 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.

Use of an appropriate protocol template such as the SPIRIT Statement is essential to ensure that all risk factors and study design requirements have been considered when planning a research project. Although the SPIRIT statement is designed for clinical trials the relevant principals can also be applied to non-interventional or health and social science research. It is recommended that researchers follow the James Lind Alliance (1) and COMET methodology (2) where appropriate.

Biostatisticians have a crucial role in ensuring that the study design, sample size, and statistical analysis plan are appropriate. They should be involved in the development of the study protocol as early as possible to ensure a well-designed and high-quality protocol. The RDGU can provide guidance in this area, including from Epworth HealthCare biostatistician who is also able to provide statistical review if an external, qualified biostatistician has developed the protocol.

3.3. Ethical Review

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)* (the *National Statement*) provides a series of guidelines to promote and inform the ethical conduct of human research (3). Activities that may come within the scope defined in the *National Statement* may also encompass areas of research that are the subject of specific legislation, such as the Federal Privacy Act (1988, 2001), the Therapeutic Goods Act (1989) and the Assisted Reproductive Technology Act (2007), as well as state and territory legislation. In these instances, those using the guidelines are also governed by federal and state legislation.

While it is important to ensure all activities are ethically sound, not all projects require review by a Human Research Ethics Committee (HREC). The National Statement describes a variety of ways in which ethical review of research involving humans may be conducted. 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 degree of risk levels can be categorised as per below (Chapter 2.1 of the *National Statement*):

- **Negligible risk** – defined by the National Statement (Section 2.1.7) as "where there is no foreseeable risk of harm of discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk."

- **Low risk** – defined by the National Statement (Section 2.1.6) as "where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more than serious than discomfort, the research is not low risk."

- **More than low risk –** Where the foreseeable risk is more than just discomfort.

The RDGU aligns with the specific ethical considerations outlined in the National Statement (Chapters 3.3, 3.4 and Section 4) to studies which involve the following aims and/or population:

- Genomic research
- Animal-to-human Xenotransplantation
- Women who are pregnant and the human fetus
- Children and young people
- People in dependent or unequal relationships
- People highly dependent on medical care who may be unable to give consent
- People with a cognitive impairment, and intellectual disability, or a mental illness
- People who may be involved in illegal activities

- Aboriginal and Torres Strait Islander peoples
- People in other countries

The majority of research projects will require review by a suitable HREC certified by the National Mutual Acceptance (NMA) initiative (*Certified HREC*). The following sections provide further guidance on the applicable HREC and non-HREC review pathways for research projects at Epworth.

3.3.1. Research Requiring HREC Review

For research involving more than low risk (i.e. more than discomfort) and/or involving overlap with legislation, review by a NHMRC Certified HREC is required. Epworth fulfils its obligations for ethical review in the following ways;

1) For studies involving a higher than negligible or low risk intervention, and in particular studies that require notification or review by the TGA (i.e. CTN/CTA) Epworth requires that they be reviewed by a Certified HREC that has demonstrated capacity to review these. In practice this will most likely be through certification of that HREC for those specific types of studies. Epworth currently has Memorandum of Understandings (MoU) with most Certified HRECs within Victoria and interstate. If your project has been approved by a HREC where a MoU has not yet been put in place, please contact the RDGU for assistance with completing the necessary agreements. It is advisable to check with the RDGU and/or the reviewing HREC for guidance on the review pathway prior to preparing the submission documentation.

   If the research project has existing ethical approval by a Certified HREC (i.e. in the case of multi-site studies), it should be possible to add Epworth as a site and Epworth researchers to the existing Ethical Approval subject to provision of all required documentation. In such cases, an additional amendment fee would be payable to the external HREC.

2) For low risk studies as defined by the National Statement, approval may be granted either by a Certified HREC or where appropriate, the RDGU. In practice, the majority of these studies will still need to go through a Certified HREC and most have expedited pathways for such reviews.

3.3.1.1 Biobanks

All biobanks must be approved by an HREC. Specifically this means that they must comply with all sections of the National Statement Chapter 3.2: Human Biospecimens in laboratory based research. Any biobanks that are intended for a therapeutic purpose must also comply with relevant regulatory requirements (Therapeutic Goods Association – TGA; Office of the Gene Technology Regulator – OGTR) and any relevant state and federal laws. It is likely that research involving human biospecimens will be of a genetic nature and so researchers should ensure that they are also compliant with the National Statement Chapter 3.3 Genomic Research.

3.3.2. 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 (s5.1.18-5.1.21), provided it does not involve study aims/populations listed in Section 4 of the National Statement. For these research projects, the RDGU will provide, on consideration of the project, written confirmation of institutional ethics approval.

In practice this means that the RDGU will organise an appropriate level of review and can produce letters that outline approval that will satisfy funding bodies and journals where necessary. This category does not apply to Audit/QA/QI projects for which there is a specific approval pathway (see below).

At Epworth non-HREC reviews are conducted by a panel consisting of at least three RDGU representatives as per our standardised process. Each reviewer must be familiar with the National Statement, have an understanding of the ethical issues that can arise in the research, are familiar with the Epworth Research Policy and Research Handbook and also have due regard to relevant privacy regulation. The reviewers then discuss the ethical considerations for the project and provide a final decision on approval. Further details on the Non-HREC review process can be provided upon request.

Please refer to SOP-RG-08 Non-HREC Review for further guidance in this process.

3.3.2.1 Clinical Case Studies

Clinical case studies or case reports are a compilation of patient information to describe a noteworthy experience or medical condition that has been observed in a clinical setting. Case studies involve the detailed analysis of a single patient or small cohort of patients. They are published because of their educational value to health professionals and students.

Clinical case studies do not necessarily require HREC review. However, as they generally include potentially identifiable patient information, consent from the patient or their representative must be obtained directly. Researchers can use SOP-RG-08 TEMPLATE-01 Case Study Consent to do so.

Please also complete SOP-RG-08 FORM-02 Case Study Notification and contact the RDGU to discuss specific case study requirements.

3.3.3. Quality Assurance / Quality Improvement Activity

A Quality Assurance (QA) or Quality Improvement (QI) activity (also known as clinical audit) is an organised data collection process designed to evaluate whether the health service being provided is what has been agreed to be best practice and/or is achieving outcomes and measures against National Standards. The NHMRC publication, *NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (March 2014)* sets out guidance for appropriate oversight of QA and evaluation activities including triggers for consideration of ethical review where required.

Epworth recognises that these activities may be included as part of undergraduate or graduate degrees and therefore will be reported as a thesis, poster, oral presentation or in a journal article. However, this does not alter the position that the primary aim of the project is to evaluate safety and quality of clinical service directly aimed at improving those services. As such the activities may require ethical consideration but this may be satisfied through non-HREC means as outlined in this handbook. In these instances, students will be required to undertake appropriate training in handling private and sensitive health information and to sign an Epworth Privacy and confidentiality declaration. The students will not be permitted to take identifiable data outside of Epworth. Please complete *Pre Quality Improvement Activity Considerations Checklist* (obtained from Quality Improvement (QI) Activities intranet page) prior to commencing any quality improvement activities.

All quality improvement activities at Epworth must be included on the Epworth Register of Quality and Improvement Projects and outline a pathway to report the outcomes to the relevant Epworth department involved.

3.3.4. Clinical Quality Registries

Clinical quality registries (CQRs) are systematic data collections established for the purpose of informing improvements in the quality of health care. Anyone wishing to set-up or include Epworth data in a CQR at Epworth must ensure a full clinical governance and management structure is in place prior to undertaking the activity as described by the ACSQHC. The Academic & Medical Services Division through the RDGU together with the Clinical Outcomes and Analytics Unit is responsible for the institutional approval and subsequent oversight of CQRs at Epworth.

Clinical registries established for the purposes of research only with no direct feedback intended to the health service as part of their clinical management are considered databanks and must conform with the requirements set out in the National Statement regarding such data collections. For further guidance on establishing a clinical registry or databank at Epworth please contact the RDGU.

To register a new CQR at Epworth please email: ClinicalQualityRegis@epworth.org.au

3.4. Researcher Credentialing

Any researcher engaged in health and medical research involving Epworth patients, staff and/or resources must be authorised to conduct research at Epworth.

The Researcher Credentialing Process ensures that all investigators conducting research at or for Epworth are qualified and authorised to do so. Research projects will not be granted governance authorisation until all listed researchers are authorised through this process.

*Note: Researcher credentialing **does not authorise clinical practice at Epworth**, and is in addition to any Epworth requirements for health professionals to undertake clinical practice.*

The Researcher Credentialing process involves providing the following documents:

- Completed Researcher Credentialing form (for clinical trials involving medicines and/or Class III or Active implantable medical devices, a Principal Investigator must be an authorised health professional who has adequate clinical and research experience and complies with all relevant training requirements and credentialing at Epworth where required).
- Current signed CV (using Epworth template)
- TransCelerate accredited Good Clinical Practice (GCP) certificate dated within 3 years (mandatory for all researchers including External Research Contractors and Research Students) (see also Section 4.1)).
- Visiting Medical Officer (VMO) Principal Investigator (PI) agreement (required for any clinical research which involves Epworth signing an agreement with other Institutions or Companies).

External Research Contractors and Research Students must also provide the following documents in addition to the abovementioned core documents:

- Intended role/research activities and whether the individual will be involved in the conduct of clinical trials under the TGA Clinical Trial Notification scheme at Epworth. Please note that external researchers are not allowed to perform medical procedures on patients at Epworth.
- External Research Contractor or Student Agreement if there is no overarching agreement in place.

For further information regarding the credentialing process please refer to: SOP-RG-04 Researcher Credentialing

3.4.1. Epworth Principal Investigator Requirements

All research being conducted at Epworth must have a site PI responsible for the safe and ethical conduct of the research project at Epworth who is an Epworth credentialed researcher. The application of a particular investigator category (i.e. PI or Sub-Investigator) for the purpose of research ethics and governance consideration does not necessarily reflect the authorship nonmenclature or ownership of the protocol.

A senior researcher/supervisor with a recognised appointment at Epworth (i.e. Employee, VMO or other Epworth accredited health professional) in addition to fulfilling the researcher credentialing requirements, 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.

Student researchers undertaking PhD or Masters Project cannot be the PI with responsibility at Epworth unless they hold appropriate accreditation and have appropriate research experience.

3.5. Resource Management

All research projects must demonstrate that institutional costings have been adequately accounted for, agreed to and can be tracked. A study budget identifies the obvious costs of the research activity (including, but not limited to estimated labour time of staff members contributing to the conduct of the study, capital equipment, review fees, statistical analysis, software, patient tests etc.) in addition to regular patient intervention, as well as in-kind support. 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. The RDGU is not responsible for ensuring that researchers have adequate funding and that they have met all of their financial and resource obligations. However, researchers will be signing a declaration that they have entered into appropriate financial arrangements with all 3rd party service providers, that they have funding for staff and consumable costs and that they have negotiated agreements with sites where the research is taking place. The RDGU will be checking that these agreements (3rd party contracts and site agreements) are in place. Failure to do so will likely be identified during routine audits and may lead to suspension of the study. Where applicable a study budget must be included in the Research Agreement (section 3.6) and will outline all the relevant costings.

Cancer Trials Australia (CTA) is contracted to offer their start-up and ongoing financial management services for commercially sponsored, collaborative and investigator-initiated clinical trials at Epworth. CTA coordinate all ethics and governance related activities as well as assist in the negotiation of budgets and contracts and provide financial management on behalf of the site. CTA also provides data to Epworth regarding feasibility, tumour groups and accrual. Please see SOP-TM-15 Working with Cancer Trials Australia for further guidance.

Where research activity undertaken by Epworth (commercially sponsored or otherwise) involves the contracting or sub-contracting by Epworth of research-related clinical services,

Epworth will engage the services of third parties consistent with its service arrangements for contracting of clinical services across the Epworth group. Epworth has service arrangements for pathology, radiology and pharmacy with the following clinical service partners:

- Pathology- Epworth Pathology - contact the Clinical Trials Coordinator
- Radiology- Epworth Medical Imaging- contact the Chief Operations Manager
- Pharmacy- Slade Pharmacy- contact the Quality and Clinical Trials Pharmacist

Whilst independent researchers are entitled to select third party service providers of their choice, Epworth encourages non-employed researchers to use the services of Epworth's clinical service partners, as service level performance is a critical aspect of these service arrangements.

Please see SOP-RG-3 Developing Contracts and Budgets for further guidance.

3.5.1. 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:

- Monetary payments from a commercial sponsor.
- In kind support or donated time from researchers, departments, laboratories or service providers.
- Donated investigational products from commercial entities.
- Grant funding from Epworth, 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 Epworth 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 review process where appropriate (see Chapter 5.4 of the National Statement).

3.5.2. Resource support and service provisions at Epworth Sites

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 Appendix A).

The Monash Partners Service Request Form can be used for internal Epworth departments or external providers where a formal service provision agreement is not in place.

3.6. Research Agreements

Where a project involves Epworth 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 Epworth Delegation Matrix (see Epworth Management Delegations Policy).

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 and
- Budget and Payment arrangements (as per section 3.5).

3.6.1. Research Agreement Type

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. Epworth is committed to reducing unnecessary repetition of paperwork and will consider umbrella service level agreements with collaborators to expedite groups of projects as appropriate. Please refer to Appendix A of SOP-RG-03 Developing Contracts and Budgets.

Legal Review of Research Agreements may be required for any agreement differing from Epworth's standard legally reviewed template agreements (e.g. for any Special Conditions in schedule 7 in CTRAs). All amendments to any current approved standard template agreement must first be discussed with the RDGU prior to seeking further review and Epworth legal approval.

3.7. Insurance and Indemnity

Epworth must be satisfied that sponsors of clinical trials have indemnity, insurance and compensation arrangements in accordance with applicable regulatory requirements. Epworth must also have arrangements to compensate participants for harm resulting from negligence

in research.

Please refer to SOP-RG-02 Clinical Indemnity and Insurance for further guidance.

3.7.1. Epworth Clinical Trial Insurance Policy

The Epworth clinical trial insurance policy provides coverage in relation to Epworth's liabilities as a trial site. Under this policy coverage extends to:

1. All employees conducting research, in accordance with the research protocol, and *for the benefit of or on behalf of Epworth**.
2. Non-employed PIs (i.e. sub-contractors) involved in Epworth initiated trials – i.e. *for the benefit of or on behalf of Epworth**.

**Please note, although insurance coverage is possible for investigator initiated trials, Epworth will NOT currently act as a sponsor for investigator initiated trials conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) scheme (see section 3.1).*

For further information on exclusions and guidance please refer to the Epworth Clinical Trials Insurance Policy.

Please be aware non-employed researchers (i.e. VMOs and External Research Contractors/Students) involved in the conduct of research activities at Epworth sites, which is not for the benefit of or on behalf of Epworth, are **not** indemnified or insured by Epworth. As such they will be required to have in place cover by their employer or hold separate insurance/indemnity cover for any liabilities that may arise (Refer to Section 3.4: Researcher Credentialing).

3.7.2. Commercially Sponsored trials

All commercially sponsored trials at Epworth 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. The minimum requirements for insurance are:

- The insurance certificate must display the full legal name of the sponsor organisation for commercially sponsored projects.
- The full legal name of the sponsor organisation must be identical to that on the indemnity certificate.
- The certificate holder must be an Australian entity.
- The territory must mention Australia is included.
- The cover per claim must be at least $10M.
- The expiry dates and trial period dates should be stated.

A current insurance certificate must be kept on file throughout the duration of an approved project.

3.7.3. 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 above in section 3.7.2 must be followed. The nature of the CRG must be clear in any application to conduct research at Epworth. The RDGU can provide further advice where required.

3.8. Data management and retention

It is the responsibility of the researcher to ensure the proper management and retention of research data during the conduct and after the completion of a research project to ensure a justification and defence of the outcomes can be provided if results are challenged. The Victorian Specific Module (VSM) outlines these requirements at the beginning of the project.

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. The length of time that data must be kept will be defined by section 2.1 of the *Australian Code for the Responsible Conduct of Research 2018 (the Code)*. For clinical trials, data must be retained for a minimum of 15 years for adult studies or 25 years for paediatric studies. For areas such as gene therapy, research data must be retained permanently.

3.8.1. 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. 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)*
- *The Guardianship and Administration Act 1986*
- *The Health Records Act 2001 (Victoria)*
- *The National Statement*
- *Australian Code for Responsible Conduct of Research 2018*

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 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 *the Code*.
- 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.

3.8.2. 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. 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 requirement so the NS 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 *Australian National Data Service (ANDS): Guideline on Publishing and Sharing Sensitive Data*.

3.9. Reporting Responsibilities and Monitoring of Research

Institutions are responsible for ensuring that any human research they conduct is run in accordance with the *Australian Code for the Responsible Conduct of Research 2018* and ethically approved and monitored in accordance with the guidance of the *National Statement*.

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*).

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. Forms on this website must be used for reporting to Epworth RDGU, where applicable.

For all research projects granted Research Governance Authorisation at Epworth, the RDGU must be notified of any new information that might warrant further review of authorisation of the project. In addition, the RDGU must be provided with the following reports:

- Annual progress reports.
- A final report at the completion of the project.

3.9.1. Reporting Safety Events

The NHMRC publication, *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016)*, sets out the requirements for the monitoring, collection and reporting of adverse events and adverse reactions that occur in clinical trials involving investigational medicinal products (IMPs) and investigational medical devices (IMDs). The guidance is also broadly applicable to all clinical trials involving therapeutic goods. Epworth aligns its reporting requirements with those of the Victorian State Government which has adopted these guidelines for all State Government HealthCare providers (2).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)

The information provided in 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.

The Epworth RDGU must be notified within 72 hours of all significant safety issues and SUSARs arising from a research project at this site. These events must be logged in RiskMan.

Please refer to SOP-TM-06 Management and Reporting of Safety Events for further guidance.

3.9.2. Data Safety Monitoring Boards

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. DSMBs are an important component of monitoring plans, but not required for all trials. 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*).

3.9.3. Reporting Serious Breaches

The NHMRC publication *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:

a) The safety or rights of a trial participant, or

b) The reliability and robustness of the data generated in the clinical trial.

This definition of serious breach differs from the definition in the *Australian Code for the Responsible Conduct of Research* (see Section 5: Research Misconduct) and is about deviations from the requirements of GCP or the clinical trial protocol.

Please see SOP-QA-02 Management of Serious Breaches and CAPA Process, SOP-RG-06 Research Misconduct, and SOP-RG-07 Research Related Complaints for further guidance.

4. Additional regulatory compliance requirements

4.1. Therapeutic Goods Administration (TGA)

The 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 (3). 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.

4.1.1. Compliance with GCP

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 condition of approval for the conduct of a clinical trial involving an investigational medicinal product (IMP) or investigational device (i.e. clinical trial as defined by GCP) (4).

Compliance with the *National Statement* is also a condition of approval for the conduct of a clinical trial involving an investigational product (4).

The TGA recognises two internationally accepted GCP guidelines:

- *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice 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 involving IMP or investigational devices are required to provide evidence of GCP training within the last 3 years (see Section 3.4 Researcher Credentialing). GCP training is also required for all other researchers at Epworth HealthCare 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 accredited GCP provider (a list of accredited providers can be found on the TransCelerate website). Monash Partners offers free TransCelerate-accredited GCP training to all paid employees of Monash Partners including Epworth employees. Further information can be found on the Monash Partners - Good Clinical Practice webpage.

4.1.2. Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) schemes

The Therapeutic Goods 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 Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) schemes are two such avenues of "exemption" that allow unapproved goods to be supplied to members of the Australian public.

All clinical trials involving an IMP or investigational device (i.e. conducted under the CTN/CTX scheme) must have an Australian trial sponsor. 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. The trial sponsor is also the entity that is responsible for submitting a CTN/CTX (5).

Please note any investigator led projects that require a CTN/CTX CANNOT be sponsored by Epworth.

Epworth employees who wish to conduct investigator initiated research under the CTN/CTX scheme are required to approach an affiliated university or CRO to be Sponsor.

VMOs who wish to conduct an investigator initiated trial under the CTN/CTX scheme are encouraged to approach an affiliated university or CRO to be Sponsor. If this is not possible, further discussion with the RDGU will be required before the study can proceed at Epworth.

Please refer to the *TGA Clinical Trials Handbook* for further information on the CTN and CTX schemes and how they may apply to your research.

The trial sponsor is responsible for the submission of the eCTN and any updates or reports (such as safety reporting) required to be submitted to the TGA during the conduct of the research project (5).

The eCTN for a clinical trial hosted at Epworth must be submitted and acknowledged by the TGA prior to commencement at Epworth.

4.2. Research involving the use of ionising radiation

In Victoria, the Department of Health and Human Services (DHHS) issues Radiation Management Licences (see DHHS Radiation webpage).

A condition stipulated by DHHS on the Radiation Management Licence is that research involving the exposure of persons to ionising radiation is carried out in accordance with the *Radiation Protection Series No. 8 - Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes* (the Code of Practice) set out by Australian Radiation & Nuclear Safety Agency (ARPANSA).

Before submitting a research project for ethics and governance authorisation involving the administration of ionising radiation (to research participants), the researcher must be familiar with their roles and responsibilities as outlined under the Code of Practice.

In particular the Code of Practice dictates that:

1. The researcher must obtain HREC approval for the conduct of the research at a site as

well as Governance authorisation from the relevant institution.

2. The researcher must prepare a submission to the reviewing HREC in accordance with its requirements. The submission must include the following information regarding radiation exposure:

   a) The reasons why it is necessary to expose research participants to ionising radiation for the purpose of the research;

   b) The radiation dose assessment and risk assessment obtained by an approved medical physicist (where above standard of care or required by the reviewing HREC);

   c) A statement confirming that the site at which the examination or procedure will be performed is actively involved in a relevant quality assurance program such as the programs of the Royal Australian & New Zealand College of Radiologists (RANZCR) or of the Australian & New Zealand Society of Nuclear Medicine (ANZSNM);

   d) The precautions to be taken to keep radiation exposure to a minimum;

   e) The written information to be given to research participants relating to the doses and risks associated with the radiation exposure; and

   f) For novel uses of radiation (e.g.: first in human trials), the arrangements for a review of radiation doses actually received and the arrangements for retention of dose records.

3. The researcher must advise the research participant to retain the information about the procedure including the radiation dose for at least five years in the case of an adult or, in the case of a child, to age 18 or for five years whichever is the longer period, so that it can be provided to researchers in any future research project involving exposure to ionising radiation.

Where a research project at Epworth involves administration of ionising radiation to a participant a fully completed '*Medical Physics Risk Assessment: Interventional, Diagnostic & Nuclear Medicine Procedures – Supporting Information'* (MPRA form) must be completed and a medical physicist report (where required) be obtained prior to HREC review.

The MPRA form is used to collate essential information regarding the use of ionising radiation in research. It helps to ensure the correct information has been made available to the right people within the institution, prior to commencing the research. It includes regulatory compliance items for research governance and risk items for HREC to consider in conjunction with the medical physicist's report and the research protocol.

The RDGU can provide a current version of the MPRA form on request.

Please refer to SOP-RG-05 Conducting Research with Ionising Radiation for further guidance.

4.3. Clinical Trial Registries

Registration of a clinical trial on a publicly accessible register is important for promoting access to information about clinical trials (6).

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.

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

For any clinical trial being conducted at Epworth, it is a requirement that trials be registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR) or an alternative ICMJE approved registry (e.g. www.clinicaltrials.gov) before trial commencement at Epworth.

4.4. Gene technology

Epworth does not currently support the conduct of research involving Germ or Somatic cell gene therapy.

4.5. Research involving excess ART embryos

Epworth does not currently support the conduct of research involving excess ART embryos.

5. Research Misconduct

The *Australian Code for Responsible Conduct of Research* describes research misconduct as "a serious breach of the Code which is also intentional or negligent".

Research misconduct includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and the failure to declare or manage a serious conflict of interest. It includes avoidable failure to follow research proposals as approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, animals or the environment. It also includes the wilful concealment or facilitation of research misconduct by others.

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

Research complaints that meet the criteria of research misconduct will be dealt with and reported according to SOP-RG-06 Research Misconduct and will be investigated in a timely manner.

6. References

If an external document is referred to in the body of the guideline has an updated version which postdates the issue date of the Epworth Research Handbook, it will be considered to apply from the issue date of that external document unless otherwise specified.

1. ***The James Lind Alliance Priority Setting Partnerships. National Institute for Health Research. .*** **[Online] http://www.jla.nihr.ac.uk/ accessed 25 November 2018.**

2. ***The COMET Handbook: version 1.0.*** **Williamson PR, Altman DG, Bagley H, Barnes KL, Blazeby JM, Brookes ST. 280, s.l. : BioMed Central, 2017, Vol. 18(Suppl 3).**

3. National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra. **[Online] 2018. https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018.**

4. NHMRC. National Certification Scheme for the ethics review of multi-centre research. [Online] https://nhmrc.gov.au/research-policy/ethics/national-certification-scheme-ethics-review-multi-centre-research.

5. Victoria Department of Health. Monitoring and reporting on an approved research project . [Online] 2018. https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting.

6. Therapeutic Goods Administration. Legislation & legislative instruments. [Online] https://www.tga.gov.au/legislation-legislative-instruments.

7. —. Australian clinical trial handbook - Guidance on GCP. [Online] Oct 12, 2018. https://www.tga.gov.au/book-page/australian-regulatory-environment.

8. Therapeutic Goods Administration. Australian clinical trial handbook - Responsibilities under the CTN and CTX schemes. [Online] Oct 12, 2018. https://www.tga.gov.au/book-page/responsibilities-under-ctn-and-ctx-schemes.

9. Australian Clinical Trials. Trial Registration. [Online] 2016. https://www.australianclinicaltrials.gov.au/trial-registration.

7. Useful Links

- **National Statement on Ethical Conduct in Human Research (2007) - Updated 2018.** https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018
- **National Certification Scheme for the ethics review of multi-centre research.** https://nhmrc.gov.au/research-policy/ethics/national-certification-scheme-ethics-review-multi-centre-research
- **Safety monitoring and reporting in clinical trials involving therapeutic goods guidance document (2016).** https://nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods
- **Data Safety Monitoring Boards (DSMBs) (2018).** https://nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods
- **Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods (2018).** https://nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods
- **Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (2018).** https://nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods
- **Australian Code for the Responsible Conduct of Research (2018) (the 2018 Code).** The 2018 Code is a principles-based document that sets out eight principles of responsible research (P1–P8) and 29 specific responsibilities for institutions (R1–R13) and researchers (R14–R29). The 2018 Code is to be implemented by all institutions by the 01 Jul 2019. https://nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018
- **NHMRC Funding research.** https://nhmrc.gov.au/funding
- **Therapeutic Goods Administration (TGA) Website – Clinical Trials:** https://www.tga.gov.au/clinical-trials
- **Therapeutic Goods Administration. (2000). Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95**) - Annotated with TGA comments. https://www.tga.gov.au/sites/default/files/ich13595an.pdf
- **Therapeutic Goods Administration. (2001). Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95).** Annotated with TGA comments. https://www.tga.gov.au/sites/default/files/ich37795.pdf
- **Australian Register of Therapeutic Goods (ARTG)** https://www.tga.gov.au/artg
- **TGA Clinical Trials Handbook.** https://www.tga.gov.au/publication/australian-clinical-trial-handbook
- **The Privacy Act 1988**. https://www.legislation.gov.au/Details/C2016C00838
- **Australian Privacy Principles - a summary for APP entities.** https://www.oaic.gov.au/agencies-and-organisations/guides/app-quick-reference-tool

- **Guidelines approved under Section 95A of the Privacy Act 1988**. https://nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988
- **The Health Records Act 2001 (Victoria).** https://www2.health.vic.gov.au/about/legislation/health-records-act
- **Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes**. https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rps8
- **Guardianship and Administration Act 1986**. Act Number 58/1986 http://www.legislation.vic.gov.au
- **Medicines Australia (MA) - Standard Clinical trial research agreements.** https://medicinesaustralia.com.au/policy/clinical-trials/
- **Medicines Australia (MA) - Indemnity & Compensation Guidelines**. https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/
- **Medical Technologies Association Australia (MTAA).** https://www.mtaa.org.au/clinical-investigation-research-agreements
- **Monash Partners GCP course.** https://monashpartners.org.au/research-facilitation/good-clinical-practice/
- **GCP providers – TransCelerate accredited**. http://www.transceleratebiopharmainc.com/gcp-training-attestation/training-providers/
- **Victorian Department of Health – Monitoring and reporting on an approved research project.** Webpage includes templates for reporting to HREC and/or institution. https://www.clinicaltrialsandresearch.vic.gov.au/monitoring-and-reporting

8. Acknowledgements

The Research Governance Framework and Guidelines for Conducting Human Research at Epworth HealthCare is based on international best practice standards. Much of the information provided in this Handbook has been derived from the following sources:

- St John of God Research Handbook
- WA Health Research Governance Procedures
- Melbourne Health procedures
- Cabrini Health Research Governance manual
- Alfred Health
- Monash Health
- Peter MacCallum Cancer Centre

Appendix A: Epworth Research Governance Approval Hierarchy - Roles and Responsibilities

It is the PIs responsibility to ensure all relevant departments are consulted and support the project. The PI must ensure evidence of all relevant approvals are available on request. The RDGU will advise PIs and staff on meeting obligations as set out in the Research Policy and Research Handbook and assist with identifying the required approvals during the initial study consultation.

Stakeholder	Examples	Key Discussion Points	Types of Projects
Directors and Executives	Medical Director (hospital specific) Clinical Institute Director (discipline specific)	• Scientific merit and design • Feasibility and participant populations • Strategic fit • Research team structure • Resources • Apparent risk (legal, reputational, financial, ethical, patient safety)	• Clinical Trials • New medical interventions • Large scale hospital wide research • Research where Epworth personnel/VMOs are participants
	*Executive General Manager (hospital/discipline specific)	• Resources • Apparent risk (legal, reputational, financial, ethical, patient safety)	• Clinical Trials • New medical interventions • Large scale hospital wide research • Research where Epworth personnel/VMOs are participants
Operational Managers	Nurse Unit Manager *Ward Manager	• Site access • Impact on personnel • Service provision beyond standard care • Consumables • Facilities • Patient and/or data access	All research which may impact their unit/ward/department
	*Head of Department Operations Manager	• Site access • Personnel • Service provision beyond standard care • Facilities • Finance • Agreements	All research which may significantly impact their unit/ward/department
Research Leaders	Research Centre Director	• Scientific merit • Feasibility and participant populations • Research team structure • Project design • Strategic fit • Risk	Availably to provide guidance and support for research conducted within their clinical institute

	*Group Director Research and Development	• Scientific merit • Feasibility and participant populations • Research team structure • Project design • Strategic fit • Risk	• Clinical Trials • New medical interventions • Large scale hospital wide research • *Can provide guidance and advice on any research project.*
Third Party Providers	• Pharmacy • Radiology • Pathology	• Service provision beyond standard care	Any research requiring their services

*If required by RDGU. Please contact research@epworth.org.au for advice if unsure.

Appendix B: Glossary of Abbreviations and Terms

Abbreviation or Term	Definition/Explanation
ARPANSA	Australian Radiation Protection & Nuclear Safety Agency
Clinical Trial	Interventional research that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (as defined by WHO). Where a clinical trial aims to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy it is subject to TGA legislation and must adhere to GCP.
CRG	Collaborative Research Group
CRO	Contract Research Organisation
EMF	Epworth Medical Foundation
GCP	Good Clinical Practice (GCP) is an international ethical and scientific quality standard provided by the International Council for Harmonisation (ICH) for designing, conducting, recording and reporting trials that involve the participation of humans.
HREC	Human Research Ethics Committee
Investigational Product	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
MA	Medicines Australia
MPRA	Medical Physics Risk Assessment: Interventional, Diagnostic & Nuclear Medicine Procedures – Supporting Information'
MTAA	Medical Technologies Association Australia

NHMRC	National Health and Medical Research Council
PI	Principal Investigator
PICF	Patient Information and Consent Form
QA	Quality Assurance
QI	Quality Improvement Activity
RDGU	Research Development and Governance Unit
Responsible Entity	An individual*, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a research project (not involving CTN/CTX).
SOPs	Standard Operating Procedures
Sponsor	An individual*, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial as defined by GCP (i.e. clinical trial involving the CTN/CTX scheme). For all other interventional research not involving an investigational product this role would be fulfilled by the 'responsible entity'. *note: Epworth will NOT be Sponsor for a clinical trial involving a CTN/CTX. Epworth employees wishing to conduct a clinical trial must enlist an appropriate entity to fulfil the role of Sponsor (see *section 4.1*)
TGA	Therapeutic Goods Administration
VMO	Visiting Medical Officer
WHO	World Health Organisation