Group Policies
- Research Policy

Policy Statement

Research is an integral part of Epworth's commitment to providing world class patient care. We aim to be nationally and internationally recognised for high quality research that supports the continuing improvement of patient care and outcomes. Research may involve the Epworth workforce as research participants or research subjects.

Research at Epworth is defined as meeting one or more of the following criteria:

- The research impacts directly or indirectly on Epworth patients – inpatients or outpatients.
- The research impacts directly or indirectly on Epworth staff – training, resourcing, service delivery
- Epworth is funding the research directly.
- The project uses significant Epworth resources.
- The research could impact on Epworth's reputation.

This policy applies to any person conducting research under this definition.

Research Governance

All individuals undertaking research at Epworth are required to ensure that the project is planned and conducted such that participants will be kept safe, that all ethical requirements are met and that they will be successful in reaching their goals.

Broadly, the term "Research Governance" has been applied to the processes that institutions, regulators, sponsors and investigators use to deliver safe and effective health and medical research involving humans.

Institutions have a responsibility to ensure that they comply with all legal and ethical regulations but also must ensure that staff involved in the conduct of the research are appropriately qualified and experienced, there are sufficient resources to conduct the research, that the patient population is available, that patient care will not be compromised by participation and that appropriate safety monitoring is in place. In addition, all institutions must determine whether the proposed studies align with their values and strategic intent.

Research Conduct and Regulatory Compliance

All research undertaken at Epworth or involving Epworth staff, patients or resources must be approved prior to commencement by the Epworth Group Chief Executive or delegate based upon their satisfaction that the following are in place;

1) Approval has been granted by the relevant person(s) in alignment with the Delegation Matrix (refer Management Delegations Policy) to approve the strategic fit and use of resources or facilities at the division where the research is happening (see Epworth Research Handbook for Research Governance Approval Hierarchy);
2) Ethical approval (as described in the Epworth Research Handbook); and
3) All appointments to Research, including external appointments of Research Contractors or Research Students are appointed in accordance with the Delegation Matrix.

The Research Development and Governance Unit (RDGU) has a role in assisting and collating the relevant approvals and all researchers should work with the RDGU to ensure that the necessary conditions for approval are met. All research must be conducted in accordance with National and international regulatory requirements and guidelines as outlined in the Epworth Research Handbook.

To ensure appropriate oversight and compliance, researchers/investigators undertaking research at Epworth or using Epworth's resources, clinical material or data off site must fall into one or more of the following categories:

- Epworth employed staff member.
- Epworth appointed medical practitioner (e.g. Visiting Medical Officer).
- Epworth appointed student (e.g. allied health, medical, nursing, psychology etc.).
- External Researcher or External Student authorised to conduct research at Epworth (via Researcher Credentialing).

The officer responsible for monitoring the implementation of this policy is the Group Director Research and Development.

Definition of research "site" at Epworth

Where research is conducted across multiple locations including non- Epworth premises and VMO private rooms, the research 'site' will be considered the place where the majority of the research will be done.

For research projects requiring notification to the Therapeutics Goods Administration (TGA), each Epworth Hospital must be listed separately on the TGA Clinical Trial Notification (CTN). Research activities conducted at additional non-Epworth locations, must be appropriate for the activity being undertaken however do not need to be listed as sub-sites.

Research ethics applications must be clear what procedures are to be done and that they will be done by qualified and experienced people in accredited facilities.

Instances in which Visiting Medical Officers (VMOs) will not be governed in rooms

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 is not involved in the oversight of this research unless requested by the VMO researcher.

In instances where the activity does not meet the definition of research at Epworth, the ethics and regulatory applications must state that Epworth is not the governing institution.

Epworth as service provider for external research

Where Epworth is being contracted as a third party service provider (i.e. for routine services) for externally driven research, a third party service level agreement between Epworth and the investigator that details the services is required.

The hospital Executive General Manager will be responsible for approving these services. The RDGU may provide advice and will note any activities where relevant to do so.

Engaging with Consumers

Epworth is committed to ensuring all research meets the needs of our patients and community and this is a core part of the Epworth Strategic Intent articulated under the Connected Care Pillar. To achieve this Epworth expects all researchers to design and conduct their research with consumer input wherever possible and to ensure that Patient Reported Outcome Measures and Experience Measures are included wherever relevant. All Clinical Trials must demonstrate genuine consumer engagement under the Australian Commission on Safety and Quality in HealthCare National Clinical trial Governance Framework.

Outcome

The intent of this document is to ensure that all research conducted under the auspices of Epworth complies with Australian legislation and guidelines as well as Epworth's and their partner organisations research guidelines and protocols.

Definitions

Research is original investigation undertaken in order to gain knowledge and understanding and make this widely available. It includes:

- Work of direct relevance to the needs of commerce and industry as well as to the public and voluntary sectors.
- Scholarship.
- The invention and generation of ideas, images, performances and artefacts including design, where these lead to new insights.
- The use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes.

Standards

Guardianship and Administration Act 1986 (Vic)

National Health and Medical Research Council. (2007 (Updated 2018)). *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018).* Commonwealth of Australia, Canberra: The National Health and Medical Research Council, the Australian Research Council and Universities Australia.

National Health and Medical Research Council. (2014). *Guidelines approved Under Section 95A of the Privacy Act 1988.* Canberra, Australia: National Health and Medical Research Council.

National Health and Medical Research Council. (2018). *The Australian Code for the Responsible Conduct of Research, 2018 (the 2018 Code).* Commonwealth of Australia, Canberra: National Health and Medical Research Council, Australian Research Council and Universities Australia.

Therapeutic Goods Administration . (2000). *NOTE FOR GUIDANCE ON GOOD CLINICAL PRACTICE (CPMP/ICH/135/95). Annotated with TGA comments.* Canberra, Australia: Commonwealth Department of Health and Aged Care.

Office of the Health Services Commissioner. (2002). *Health Records Act 2001 (Vic) Statutory Guidelines on Research issued for the purposes of Health Privacy Principles 1.1(e)(iii) & 2.2(g)(iii).* Retrieved from https://hcc.vic.gov.au/sites/default/files/media/statutory_guidelines_on_research_2002.pdf

Relevant National Safety and Quality Health Service Standards 2nd Ed.

- ☒ Clinical Governance
- ☒ Partnering with Consumers
- ☐ Healthcare Associated Infections
- ☐ Medication Safety
- ☐ NSQHS Standards are not applicable
- ☐ Comprehensive Care
- ☐ Communicating for Safety
- ☐ Blood Management
- ☐ Recognising & Responding to Acute Deterioration

Linked PP

- Management Delegations Policy
- Epworth Research Handbook

Departments

- Organisational Wide

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