

Clinical Research Nurse (CRN)

AUSTRALIAN STANDARDS
FOR PRACTICE



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CONTENTS

Foreword	4
The clinical research nurse (CRN)	4
Background	4
Scope and purpose of standards	4
Differentiating the clinical research nurse from the nurse researcher	4
Language and terminology	5
Standards	6
Standards framework	6
The clinical research nurse specialty	6
STANDARD 1	8
STANDARD 2	10
STANDARD 3	12
STANDARD 4	14
STANDARD 5	16
STANDARD 6	18
STANDARD 7	20
References	22
Acknowledgements	23

Foreword

The Australian College of Nursing (ACN) takes great pleasure in endorsing the inaugural Clinical Research Nurse (CRN) Australian Standards for Practice (the Standards). The Standards represent our commitment to advancing nursing leadership and advocacy of professional practice for Australian CRNs.

Developed through a consultative process, the Standards aim to improve recognition of the CRN's specialised role, which provides an invaluable contribution to advancing health care and patient-related outcomes through research. Although the CRN role has been described in nursing literature as early as 1910 (Ellicott, 1910), associated professional standards have not previously existed in an Australian setting. In acknowledging the CRN's unique skill set and expertise, the Standards define a new era in ensuring future recognition of the CRN role within Australia. The Standards will support the development of career pathways and formal award recognition and help shape a future national network of clinical research nursing professionals.

The clinical research nurse (CRN)

The clinical research nurse is a specialised registered nurse (RN) who combines clinical nursing expertise with research knowledge and skills. The CRN facilitates the delivery of rigorous, high-quality clinical research to improve health care outcomes, the research participant experience, and treatment pathways. Collaborating with clinical and research colleagues, the CRN integrates research with holistic nursing care.

Background

Scope and purpose of standards

The Australian Standards for Practice have been developed by CRNs for RNs working in clinical research in Australia. The Standards are intended to provide a definition of the specialty of clinical research nursing in Australia. Additionally, these Standards highlight the CRN's role in providing nursing care for clinical research participants, their support networks, and facilitating clinical research.

The Standards reference and extend upon the Nursing and Midwifery Board of Australia *Registered Nurse Standards for Practice* (Nursing and Midwifery Board of Australia, 2016). The Standards have been developed following an international and national scoping review of the CRN role, including the *Whitehouse Report* (Whitehouse & Smith, 2018), UK Clinical Research Facility *Research Nurse Competency Framework* (Competency Working Group, 2011), Joint Task Force (JTF) *Core Competency Framework for Clinical Research Professionals* (Joint Task Force for Clinical Trial Competency (JTF), 2020) and the International Association of Clinical Research Nurses (IACRN) *Scope and Standards of Practice* (Browning et al., 2016).

Contemporary Australian nursing standards and research competencies have been reviewed, including the Australian College of Critical Care Nurses (ACCCN) *Practice Standards for Specialist Critical Care Nurses* (Chamberlain et al., 2018) and the National Health and Medical Research Council (NHMRC) *Competencies for Australian Academic Clinical Trialists* (National Health and Medical Research Council, 2018). The Standards have been developed with support from the Australian College of Nursing over 12 months, including an open consultation period.

This document is intended to define Standards of Practice for CRNs in Australia, with recognition of the continuum of knowledge and skills development within the specialist CRN role and the diversity of research environments. The authors recognise that an individual CRN's practice may extend beyond these Standards. However, the CRN career pathway is yet to be universally recognised and described across Australia. The Standards are not intended to be interpreted as competency standards but may inform the development of specialist Australian CRN competencies and scope of practice guidelines in the future.

Differentiating the clinical research nurse from the nurse researcher

It is essential to recognise that the Standards directly reflect the role of the CRN as distinct from the unique role of the nurse researcher. The nurse researcher typically leads their research project(s) or leads multidisciplinary research teams on systematic enquiry designed to develop and progress knowledge of nursing practice or policy development. Conversely, the CRN delivers rigorous, high-quality clinical research to improve health care outcomes, the research participant experience, and treatment pathways, acting as a patient advocate to ensure ethical and efficient care.

Language and terminology

In recognition of the evolving nomenclature in clinical research, we seek to provide clarity regarding the language and terminology used within the Standards.

The Standards have been written with the intent of inclusivity and respect. Certain terms act as ‘umbrella’ expressions to capture similar concepts and provide consistency.

Glossary

Clinical care/ nursing care	Holistic nursing care provided to research participants, including direct care, health promotion, education, and advocacy.
Clinical research	Health and medical research, including clinical trials, that involve people and their communities. There are two main types of clinical research - observational studies and clinical trials. The Standards apply to the CRN across this spectrum of research.
Consumer	Patients, potential patients, carers, and people using health care services. Consumers can also be people who represent the views and interests of a consumer organisation, a community, or a broader constituency.
Decision maker	This umbrella term refers to a defined substitute decision maker (SDM) appointed by the Court or Guardianship Board, or persons responsible, as identified, according to a hierarchy by the treating medical practitioner when no SDM has been appointed. Each state and territory has independent regulatory and legislative conditions (Mental Health Coordinating Council, 2020).
Health care	Includes primary, secondary, tertiary and quaternary care.
ICH GCP	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guideline. An internationally accepted standard for the designing, conducting, recording and reporting of clinical trials (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), 2016).
Participants	Individuals who participate in health and medical research, e.g., healthy volunteers, patients, and clinicians.
Primary care	The first point of contact that an individual has with the health system. It relates to the treatment of non-admitted patients in the community (The Department of Health and Aged Care, 2021).
Project management	The application of knowledge, skills, tools, and techniques to conduct activities to meet the project requirements. It involves expertise in scope, time, cost, quality, risk management, communications, and stakeholder management (Australian Public Service Commission, 2021).
Protocol	A document specifying approved research design, methodology, conditions for participation, study, and safety procedures. Research must be conducted in compliance with this document.
Quaternary care	Advanced levels of medicine which are highly specialised and not widely accessed (New South Wales Health, 2016).
Research waste	Research outcomes with no societal benefits (Glasziou, 2018).
Secondary care	Services provided by a medical specialist or health professional that is not the first point of contact for a patient (Queensland Health, 2019).
Support network	Those who provide social and/or care support to participants, e.g., families, communities, caregivers, and designated treatment decision-makers.
Tertiary care	Highly specialised health care including complex medical or surgical procedures provided as a hospital in-patient on referral from a primary or secondary health professional (Queensland Health, 2019).

STANDARDS

Standards framework

The CRN Standards are described by a framework of elements and associated performance indicators. The elements define each standard's core values and activities, with performance indicators providing examples of the practical application of the elements. The performance indicators have been selected to be applicable and representative, but not exhaustive, within the range of sectors and settings of CRN practice. They are not designed to be measurable, as this should be determined at an organisational level, commensurate with the research area of practice.

The clinical research nurse specialty

Bridging research and clinical care

The CRN demonstrates advanced communication and care coordination competencies to provide nursing care to research participants. The CRN applies problem-solving skills to navigate complex clinical care that integrates research and clinical activities to meet the needs of research participants and their support networks within the parameters of the research protocol. The CRN promotes a collaborative multidisciplinary team approach to care within the clinical research environment with research participants as critical partners. The CRN empowers the translation of research results into clinical practice, facilitating understanding of research outcomes across the stakeholder network. The CRN continually integrates requirements for research integrity and data quality with the clinical and safety needs of each participant. Clinical and research priorities are expertly balanced, with the safety and wellbeing of participants being paramount.

Specialist research skills

Through knowledge of local, national, and international legislation, policy, regulations and guidance, the CRN facilitates research activities within a complex clinical, scientific, methodological, cultural, ethical, legal, and regulatory environment. The CRN demonstrates expert organisational skills to coordinate or manage clinical and research activities, often across concurrent projects. The CRN navigates operational and administrative

processes to enable research, fostering collaborative relationships with clinical and research colleagues, business and organisational stakeholders, health care consumers, and professional partners.

A diverse role

The CRN role is agile, flexible, and effective across various settings, including health care, academia, and industry. The CRN role includes different responsibilities across clinical and research workstreams, depending upon the setting and sector (primary through to quaternary health care). The integration of clinical, professional, organisational, and administrative responsibilities is central to the role of the CRN.

Beginner to advanced practitioner

As within all specialist nursing roles, there is a continuum of expertise within the CRN specialty. The Standards recognise the specialist skills required for the role, from beginner to advanced level. They recognise that the CRN operates with a high degree of autonomy, with many CRNs leading the administration and management of clinical research from concept to publication, in unison with the management of research teams and resources. Finance, grant management, and contract negotiation responsibilities often form part of the CRN role for more advanced practitioners. The experienced CRN also acts as an expert resource and mentor for entry-level and non-CRN colleagues, promoting the role and purpose of clinical research to inform future practice.

CLINICAL RESEARCH NURSE (CRN): AUSTRALIAN STANDARDS FOR PRACTICE

STANDARD 1

Applies critical thinking and research knowledge to nursing practice, clinical care, and management of research participants.

STANDARD 2

Establishes and maintains respectful, diverse, and collaborative professional relationships to promote person-centred research.

STANDARD 3

Maintains proficiency of practice in both clinical and research disciplines.

STANDARD 4

Plans nursing care for clinical research participants, applying evidence-based clinical skills and validated and standardised research processes.

STANDARD 5

Delivers safe, appropriate, responsive, and cohesive care to clinical research participants.

STANDARD 6

Applies specialised research and management skills to enable the delivery of high-quality clinical and research practice.

STANDARD 7

Contributes to the advancement of evidence-based health care and the clinical research nurse specialty.

STANDARD 1:

Applies critical thinking and research knowledge to nursing practice, clinical care, and management of research participants.

The CRN uses a variety of critical thinking strategies, best available evidence, and specialised research knowledge in leading the delivery of research and provision of nursing care to research participants. The CRN is responsible for coordinating safe and competent care within person-centred, protocol-driven, and evidence-based frameworks.

Element 1.1

Applies the best available evidence-based nursing and research knowledge to assess, analyse, and guide practice.

Performance indicators

- Provides comprehensive, safe, and quality nursing care to deliver research-specific study procedures.
- Provides holistic health care to research participants.
- Provides support and education to research participants and their support networks.
- Demonstrates professionalism and compassion when managing research participants' critical and complex care needs.

Element 1.2

Uses ethical decision-making in clinical research and care delivery, applying knowledge of the principles of local, national, and international legislation, policy, regulatory, and guidance documents.

Performance indicators

- Reviews the participant's understanding of information regarding clinical research opportunities and respects the decision-making process.
- Facilitates or leads the informed consent process with participants (or relevant decision makers) in accordance with Good Clinical Practice (ICH GCP) (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH, 2016) and the National Statement on Ethical Conduct in Human Research (National Health and Medical Research Council, 2018), and other legal and regulatory requirements.
- Continually assesses the care and wellbeing of the participant and the research protocol's requirements, ensuring the participant's safety and wellbeing remains the primary consideration.



Element 1.3

Actively participates in practice development and continuous improvement initiatives in alignment with research, clinical regulations, and guidelines.

Performance indicators

- Manages risk through implementing risk controls, including quality and monitoring activities.
- Identifies opportunities for improvement in the clinical research process.
- Develops skills to access and integrate digital technologies in research and health care practice.
- Uses reflective practices to review understanding of how evidence-based knowledge, actions, experience, feelings, and beliefs shape practice.

STANDARD 2:

Establishes and maintains ethical, respectful, diverse, and collaborative professional relationships to promote person-centred research.

CRN practice is underpinned by effective professional relationships with research participants, multidisciplinary colleagues, and stakeholders across clinical, research, and service provision teams.

Element 2.1

Respects the expertise and experience of individuals who engage in health and research activities.

Performance indicators

- Promotes and utilises effective communication strategies that are inclusive of an individual's dignity, culture, values, beliefs, and rights.
- Advocates on behalf of research participants in an ethical manner that respects the person's autonomy and rights.
- Safeguards a research participant's inherent right to privacy and confidentiality in alignment with policy and best practice guidelines (Services Australia, 2022).

Element 2.2

Promotes person-centred research approaches and inclusive study design.

Performance indicators

- Facilitates and advocates for the inclusion of the consumer's voice in research prioritisation, design, and conduct across the research life cycle.
- Raises awareness of clinical research within clinical care teams to enhance opportunities for research involvement and participation, particularly for under-served and under-represented populations.
- Collaborates with stakeholders to ensure the views of consumers, their support networks, and communities are included in research prioritisation, design, engagement, and dissemination.



Element 2.3

Establishes and maintains effective relationships with multidisciplinary team colleagues, clinical care teams, consumers, clinical and academic stakeholders, and other partners.

Performance indicators

- Acts as a specialist resource for clinical and research colleagues to promote the safe and ethical conduct of research activities.
- Shares research knowledge and practical skills to support embedding research alongside evidence-based and person-centred care.
- Promotes a cross-disciplinary culture of innovation and learning through leadership (and mentorship) of staff directly or indirectly involved in clinical research.

STANDARD 3:

Maintains proficiency of practice in both clinical and research disciplines.

The CRN is responsible for maintaining professional nursing registration and is accountable for ensuring they work safely and competently within their scope of practice. The CRN must demonstrate ongoing professional development and currency of clinical practice proficiency in specialist clinical research skills and knowledge.

Element 3.1

Applies knowledge of relevant nursing legislation and ethical frameworks, professional standards, policies, and procedures for clinical and research practice.

Performance indicators

- Maintains current nursing registration and ensures currency and competency of clinical practice nursing skills.
- Practises under the auspices of the Nursing and Midwifery Board of Australia Registered Nurse Standards for Practice and within their own scope of practice.
- Establishes and maintains knowledge of and certification in ICH Good Clinical Practice (ICH GCP).
- Contributes to establishing and maintaining clinical and research environments conducive to safe, quality care that maintains fidelity to clinical research methodologies and practice.

Element 3.2

Understands, navigates, and complies with legislation, regulatory policy, and guidelines relevant to their clinical research setting.

Performance indicators

- Contributes to, and may coordinate, the application processes for ethical, regulatory and governance approvals associated with clinical research activity and ensures adherence to ongoing reporting requirements.
- Identifies and addresses gaps in study design or processes that may impact the safe and high-quality conduct of research.
- Provides support and advice regarding ethical and regulatory authorisations to colleagues establishing clinical research activities, including those new to research.

Element 3.3

Accepts accountability for decisions, actions, behaviours, and responsibilities inherent in their role and delegated responsibilities.

Performance indicators

- Undertakes training for specialist tasks within the CRN role, including (but not limited to) compliance, research governance and data management, project management, informed consent processes, and safety event reporting.
- Establishes and maintains accurate, comprehensive and timely documentation of training, planning, decision-making, actions and evaluations of clinical and research activities.
- Coordinates, contributes to or leads the effective management of study interventions.
- Assesses, maintains, and monitors the safe and effective functioning of clinical trial-related equipment and consumables.

STANDARD 4:

Plans nursing care for clinical research participants, applying evidence-based clinical skills, and validated and standardised research processes.

The CRN is responsible for the development, implementation, coordination, documentation, and evaluation of individual research participants' plans of care in accordance with the approved research design and regulatory requirements.

Element 4.1

Plans safe and effective nursing care with consideration of the clinical research protocol/ methodology and the CRN's scope of practice.

Performance indicators

- Effectively plans and coordinates clinical research participation and clinical follow up, prioritising treatment and care according to research requirements and participants' needs.
- Performs focused health assessments and undertakes appropriate nursing interventions as necessary.
- Contributes a nursing perspective to clinical research projects to ensure appropriate workflows and prioritise clinical needs.

Element 4.2

Plans care and research engagement with respect for all cultures and experiences, which includes responding to the role of family and community that underpins the health of Aboriginal and Torres Strait Islander peoples and people of culturally and linguistically diverse backgrounds.

Performance indicators

- Actively seeks to understand the cultures and experiences of participants, applying this awareness and knowledge to clinical care and research interactions.
- Advocates for person-centred approaches to research participation.
- Optimises strategies to promote inclusive care and research opportunities for underserved and underrepresented populations.
- Uses knowledge of research processes and methodology to enhance accessibility to research for all populations, including consideration of how to address barriers that may limit participation.



Element 4.3

Supports participants in informed decision-making and promotes autonomy regarding participation in clinical research, including an emphasis on the voluntary nature of participation, ongoing consent process, and options for withdrawal.

Performance indicators

- Applies nursing and research communication skills and training to ensure participants receive, understand, and consider clinical research information prior to giving informed consent.
- Works with participants to continually assess the individual's risk/benefit assessment of research participation, supporting participants to re-evaluate consent decisions, if required.
- Ensures continuity of care for participants who complete or withdraw (or are withdrawn) from clinical research.

Element 4.4

Enhances the participant's understanding and research skills and knowledge within the scope of practice.

Performance indicators

- Demonstrates a thorough understanding of the clinical or health topic of research and the research objectives.
- Accurately and transparently communicates the risks and benefits of research participation within scope of practice and with consideration and awareness of an individual's experiences, values, and beliefs.
- Within scope of practice, provides information and education regarding alternatives to research participation, including standard clinical care pathways.
- Uses research interactions as opportunities to provide holistic education and support to participants and their support networks.

STANDARD 5:

Delivers safe, appropriate, responsive, and cohesive care to clinical research participants.

The CRN draws on clinical and organisational skills to plan and implement care for research participants, with a focus on balancing the requirements of the research with the clinical care requirements of the participant.

Element 5.1

Prioritises safety and wellbeing in the delivery of care for research participants.

Performance indicators

- Ensures research requirements are aligned to clinical needs, effectively evaluating, prioritising, and triaging care.
- Safely administers and monitors investigational therapies based on accurate knowledge of the product (including investigational devices) and potential interactions with concurrent therapies the research participant receives.

Element 5.2

Identifies and appropriately responds to clinical concerns, liaising with clinical colleagues and the multidisciplinary team to ensure timely referral or review of research participants' clinical and research care.

Performance indicators

- Uses nursing knowledge and assessments to identify and communicate changes in the participant's condition that require assessment or intervention with a holistic approach to care.
- Assesses and implements appropriate nursing care pathways related to adverse events experienced during a clinical trial, regardless of causality.
- Continuously monitors research participants for adverse events, working to mitigate and manage harm. Expedites adverse event reporting to appropriate authorities in keeping with the research protocol, relevant guidelines, and regulatory and organisational requirements.

Element 5.3

Provides a continuum of care that supports participants to retain autonomy over research and clinical care decisions.

Performance indicators

- Communicates participant needs, priorities, obstacles, opportunities, and logistics of participation to the clinical and research teams (and other stakeholders), advocating for an individualised approach.
- Led by the participant, engages and involves the participant's support network in decisions relating to the delivery of care and research involvement, especially where existing care pathways are impacted.
- Builds rapport and maintains effective communication with participants and their support networks

Element 5.4

Adheres to established local, national, and international clinical research and trial policies, guidelines, and best practice standards when making complex and informed independent decisions related to research and clinical care delivery.

Performance indicators

- As relevant, ensures informed consent has been received prior to implementation of any research related procedures and advocates effectively for vulnerable populations.
- Considers the existence of real or perceived conflicts or duality of interests for stakeholders, particularly those of the research participant.
- Exercises knowledge of research regulatory processes to facilitate and maintain high-quality data integrity and care delivery practice.
- Recognises when input is required from clinical or research colleagues, consciously working within the scope of research and clinical practice.

STANDARD 6:

Applies specialised research and management skills to enable the delivery of high-quality clinical and research practice.

The CRN is required to apply traditional and innovative project management methods, organisational skills, and knowledge to support the design and conduct of clinical trials and research projects, ensuring the care of the participant is in unison with the delivery of research objectives.

Element 6.1

Provides specialised clinical and research expertise to guide discussions on key feasibility factors, including study suitability, adequacy of organisational resources, competencies, capabilities, and access to target population.

Performance indicators

- Participates in decision-making for proposed clinical research studies within their area of practice, considering resource and capacity availability to support the proposed research.
- Coordinates and/or manages clinical research project(s) across the study lifecycle to ensure resources, risk controls, and project outcomes are effectively and efficiently managed and delivered.
- Manages a research program or project's operational, financial, organisational or business responsibilities, commensurate with role and level.
- Undertakes training in project and data management within the clinical research setting.

Element 6.2

Advocates for sustainable, person-centred approaches to planning and management of research projects.

Performance indicators

- Facilitates and engages stakeholders, including the general public, in research co-design, planning and effective implementation to reduce research waste and promote sustainable research.
- Applies nursing care management principles to research project management and care planning for research participants.
- Ensures the feasibility review has included consideration of sustainable and appropriate use of clinical and research resources.
- Minimises waste and promotes sustainable research practice to foster a culture of responsible environmental decisions in research-related health care.



Element 6.3

Collaborates with multidisciplinary colleagues and stakeholders to facilitate planning for integrated research and clinical care, alongside the delivery of research objectives.

Performance indicators

- Communicates effectively with research and clinical stakeholders to facilitate clinical oversight, safety processes and procedures, and the appropriate integration of research activities into routine care (where possible).
- Demonstrates leadership, negotiation, and communication skills to optimise project milestones and objectives management.
- Ensures clearly documented delegation of research project activities and responsibilities.
- Facilitates effective monitoring processes to ensure project risk and quality are proactively managed across the project's lifecycle and the rights and welfare of research participants are protected.
- Utilises reflective practice to facilitate safety, quality, and risk identification and management.

STANDARD 7:

Contributes to the advancement of evidence-based health care and the clinical research nurse specialty.

The CRN contributes to building evidence-based health care and advancing the CRN specialty through coordination and delivery of high-quality research. With their specialised research skill set, the CRN is optimally positioned to enable a research-active workplace culture and to lead professional research development opportunities.

Element 7.1

Provides specialised clinical and research coordination skills and expertise to deliver research that addresses important clinical questions and gaps in health care knowledge.

Performance indicators

- Ensures research is conducted per all applicable local, national, and international regulatory, policy, and guideline requirements to collect high-quality, reliable, replicable, and valid research data.
- Participates in the review of proposed or planned research to inform the design and delivery of high-quality clinical research studies.
- Encourages and actively promotes a research-active culture.
- Fosters links with nurse researchers to support research capabilities within the nursing profession.

Element 7.2

Contributes to developing and implementing safe, effective, inclusive, and person-centred clinical research practices.

Performance indicators

- Enables and supports consumer involvement in the research process.
- Contributes to developing clinical research standard operating procedures (or similar) to ensure standardised, reliable research practice and data generation, aligned with the study protocol/methodologies.
- Aligns practice with relevant National Safety and Quality Health Service Standards (Australian Commission on Safety and Quality in Health Care, 2017) and the Clinical Trials Governance Framework (Australian Commission on Safety and Quality in Health Care, 2022), relating to health and care research in Australia.



Element 7.3

Fosters best practice and knowledge sharing across the CRN specialty and advocates for growth and recognition of the role.

Performance indicators

- Provides positive role-modelling, leadership, and mentorship for the CRN role.
- Supports advocacy and advancement of the role of the CRN, including advocacy for education and training opportunities, in public and professional forums.
- Contributes to local professional networks and support frameworks for CRNs.

Element 7.4

Pursues personal and professional development for self.

Performance indicators

- Demonstrates professional development and education in clinical and research domains.
- Maintains clinical competencies and mandatory training related to nursing registration and clinical roles.
- Participates in peer-support activities, networks, or relationships to ensure own wellbeing and personal and professional development.

REFERENCES

- Australian Commission on Safety and Quality in Health Care. (2017). *National Safety and Quality Health Service Standards* (2nd ed). Australian Commission on Safety and Quality in Health Care. <https://www.safetyandquality.gov.au/sites/default/files/migrated/National-Safety-and-Quality-Health-Service-Standards-second-edition.pdf>
- Australian Commission on Safety and Quality in Health Care. (2022). *The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials*. Australian Commission on Safety and Quality in Health Care. https://www.safetyandquality.gov.au/sites/default/files/2022-05/final_design_-_national_clinical_trials_governance_framework_and_user_guide_-_30_may_2022.pdf
- Australian Government Department of Health and Aged Care. (2021). *Primary Care*. Australian Government. <https://www1.health.gov.au/internet/main/publishing.nsf/Content/primarycare>
- Australian Public Service Commission. (2021). *Effective Project Management*. Australian Government. <https://www.apsc.gov.au/initiatives-and-programs/workforce-information/taskforce-toolkit/project-management/effective-project-management>
- Browning, S., McCabe, M., Mehring, T., Williams, M., Borgiasz, S., Johnson, S., Jones, C., & Turbini, V. (2016). *Clinical Research Nursing: Scopes and Standards of Practice*. American Nurses Association.
- Chamberlain, D., Pollock, W., & Fulbrook, P. (2018). ACCCN Workforce Standards for Intensive Care Nursing: Systematic and evidence review, development, and appraisal. *Australian Critical Care*, 31(5), 292-302. doi.org/10.1016/j.aucc.2017.08.007
- Competency Working Group. (2011). *Competency Framework for Clinical Research Nurses: A Tool to Promote Patient Safety and Quality Data*. NIHR Cambridge Clinical Research Facility. https://cambridge.crf.nihr.ac.uk/wp-content/uploads/2015/04/Research_Nurse_Competency_Framework_-_Version_2_-_Full_-_Oct_2011.pdf
- Ellicott, N. P. (1910). The Hospital of the Rockefeller Institute for Medical Research. *Johns Hopkins Nurses Alumnae Magazine*, 9(4), 209-213.
- Glasziou, P., & Chalmers, I. (2018). Research waste is still a scandal—an essay by Paul Glasziou and Iain Chalmers. *BMJ*, 363: k4645. doi:10.1136/bmj.k4645
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2016). *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)*. https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
- Joint Task Force for Clinical Trial Competency (JTF). (2020). *JTF Core Competency Framework for the Clinical Research Professional Version 3.1*. https://mrctcenter.org/clinical-trial-competency/wp-content/uploads/sites/5/2020/03/2020-02-20_Version-3.1_JTF-Framework-for-posting.pdf
- Mental Health Coordinating Council. (2020). *Mental Health Rights Manual Chapter 5 Section A: Substitute Decision Making*. Mental Health Coordinating Council Australia. <https://mhrm.mhcc.org.au/chapters/5-substitute-decision-making-and-capacity/5a-substitute-decision-making/>
- National Health and Medical Research Council. (2018). *Competencies for Australian Academic Clinical Trialists*. Canberra: National Health and Medical Research Council. <https://www.nhmrc.gov.au/sites/default/files/documents/attachments/competencies-for-australian-academic-clinical-trialists.pdf>
- National Health and Medical Research Council (NHMRC), Australian Research Council (ARC) & Universities Australia (UA). (2018). *National Statement on Ethical Conduct in Human Research 2007*. Canberra: Commonwealth of Australia. <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>
- New South Wales Health. (2016). *Annual Report 2015-16*. New South Wales Government, Australia. <https://www.health.nsw.gov.au/annualreport/Publications/2016/compliance-checklist-glossary.pdf>

Nursing and Midwifery Board of Australia. (2016). *Registered Nurse Standards for Practice*. <https://www.nursingmidwiferyboard.gov.au/codes-guidelines-statements/professional-standards/registered-nurse-standards-for-practice.aspx>

Queensland Health. (2019). *Health System*. Queensland Government Australia. https://www.health.qld.gov.au/_data/assets/pdf_file/0021/714243/5.-Health-system.PDF

Services Australia. (2022). *Your Right to Privacy*. Australian Government. <https://www.servicesaustralia.gov.au/your-right-to-privacy?context=1>

Whitehouse, C. L., & Smith, H. A. (2018). *The Whitehouse Report: Review of research nursing and midwifery structures, strategies and sharing of learning across the UK and Ireland in 2017*. The Florence Nightingale Foundation, 3.

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