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# COMPETENCIES FOR AUSTRALIAN ACADEMIC CLINICAL TRIALISTS

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## Background

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A well trained health workforce is essential to performing high quality clinical trials. While on the job training has traditionally been the pathway by which students and early career researchers gained mastery of research skills, a global community of researchers, governments and companies have recognised the need for greater consistency in the content of learning and educational resources and in their delivery and assessment. As part of its work to improve the conduct of clinical trials in Australia, the National Health and Medical Research Council (NHMRC), in conjunction with the Department of Industry, Innovation and Science (DoIIS), developed a range of education resources for clinical trial proponents, research governance officers and members of the public. These include a series of eLearning Modules for clinical trialists and research governance officers and a Vocational Education and Training (VET) curriculum for research governance officers.

During the preparation of these resources, NHMRC identified a gap in the educational resources for academic clinical trial researchers and educators and worked with a group of them to develop the core competencies required for academic/investigator-initiated clinical trialists.

These competencies were based on a pre-existing framework developed for commercially-sponsored studies by the US-based Clinical Trials Transformation Initiative (CTTI, <https://www.ctti-clinicaltrials.org>), and by TransCelerate Biopharma (TransCelerate) (<http://www.transceleratebiopharmainc.com>). It is envisaged that NHMRC-developed competencies will eventually be incorporated into higher education and general education frameworks in Australia, with life-long learning and training supported by initiatives developed by groups such as CTTI, TransCelerate and Praxis Australia (<http://praxisaustralia.com.au/>).

This activity complements the work being carried out by an Organisation for Economic Co-operation and Development (OECD) committee, and aligns with the Harmonized Core Competencies developed in the US as part of an initiative led by the Multi-Regional Clinical Trial Centre at Harvard University.

### CTTI work

The Clinical Trials Transformation Initiative (CTTI) is a public-private partnership established to develop and drive adoption of practices that increase the quality and efficiency of clinical trials. An important CTTI output is a [Principles Document](#) on quality in clinical trials, developed through the *Quality By Design* project, which examines a range of 'critical to quality' factors in research design and execution. Having considered this document, and other work of CTTI, the competencies provide evidence of a desire for new clinical trialists to focus on quality in research design and undertake early assessment of trial feasibility.

## OECD work

In 2011 the OECD's Global Science Forum established a Working Group to Facilitate International Co-operation in Non-Commercial Clinical Trials (Working Group). The Working Group held a roundtable in Berlin in 2011 and, in October that year, published a policy report: *Facilitating International Cooperation in Non-Commercial Clinical Trials*. This document sought to address three main challenges:

- the excessive administrative complexity of clinical trial processes
- the desirability of introducing a risk-based approach to the management of clinical trials, and
- the need to improve the education and training support as well as the infrastructure framework in clinical research and the involvement of patients.

The policy report recommended that member nations 'develop a concept of Global Core Competencies for clinical research trials' and that these global core competencies should:

“...be developed as a compendium of required knowledge and skills for investigators and other members of the clinical research team, adapted to their different responsibilities and roles. Standardised as well as mutually and internationally recognised accredited qualifications in patient-oriented clinical research should also be defined”.<sup>1</sup>

NHMRC's development of its own competencies has been undertaken in a way that is consistent with, and supportive of, the work of the OECD.

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1 <http://www.oecd.org/science/sci-tech/49344626.pdf>

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## Purpose and Use of the Competencies

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These competencies are intended to be used in the development of detailed curricula and training courses by universities and other educational institutions. Targeted toward those likely to be involved in the design, conduct and management of academic clinical trials, the intended audience for the competencies includes undergraduate and post-graduate students as well as individuals undertaking on-the-job training or continuing professional development. The competencies have been designed to support graduated and stratified learning with three competency levels and three roles.

The three competency levels are:

- Level 1** – Ability to apply knowledge and skills to demonstrate autonomy, judgement and limited responsibility in known or changing contexts and within established parameters.
- Level 2** – Ability to apply knowledge and skills to demonstrate autonomy, judgement and defined responsibility in contexts that are subject to change and within broad parameters to provide specialist advice and functions.
- Level 3** – Ability to apply knowledge and skills to demonstrate autonomy, expert judgement, adaptability and responsibility as a practitioner and leader.

The three roles specified in the competencies are:

**Site staff** – all staff involved in a trial, with a particular emphasis on the role of the Clinical Research Co-ordinator.

**Site Principal Investigator (PI)** – the PI at a given site, who may or may not be the trial designer.

**Lead Principal Investigator** – the PI who has designed the clinical trial and who takes overall responsibility for it.

The competencies focus on seven core areas:

- scientific concepts and research design
- ethical concepts and participant safety considerations
- feasibility assessment and study initiation
- clinical trials conduct
- study and site management
- leadership, teamwork and communication
- data management, privacy legislation and study closure.

The tables detail the competencies, how competence can be demonstrated and the competency levels that are required for the three roles identified above.

A participant-focused approach was adopted in the design of the competencies, and the design and delivery of courses should have participant/patient safety as the primary consideration.

Further information on the development of competencies can be found at:

<https://www.nhmrc.gov.au/research-clinical-trials-nhmrc-clinical-trials-initiatives>.

Further information on competency levels as developed by the Australian Quality Training Framework (VET Framework) can be found at: <https://www.training.com.au/aqtf2007/>.

# Clinical Trial Competencies

## Broad area

Study design - Scientific concepts and research design

Involves knowledge of scientific concepts related to the design and analysis of clinical trials and which underpin the use of a particular intervention to address a specific research question.

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
Theories underpinning a range of therapies, devices and the intervention development process.	<ul style="list-style-type: none"> <li>Identify and describe different treatment modalities including drugs, devices, biologicals, behavioural interventions; and disciplines including pathophysiology, pharmacology, toxicology and psychology as related to medicines and intervention discovery and development.</li> <li>Explain the intervention development process.</li> <li>Differentiate research from innovation, routine clinical care, QA and audit.</li> <li>Explain how modification of existing processes, rather than developing new processes, could enhance eventual uptake of research findings.</li> </ul>	Level 1	Level 2	Level 3
Developing good clinical research questions that are potentially testable through a systematic review of peer-reviewed literature.	<ul style="list-style-type: none"> <li>Understand the research need.</li> <li>Articulate the elements of a good research question and how it can be tested.</li> </ul>	Level 1	Level 2	Level 3
Developing good clinical research questions that are potentially testable through a systematic review of peer-reviewed literature.	<ul style="list-style-type: none"> <li>Name and describe the principles of a systematic literature review and how it contributes to the determination of possible research questions and inclusion/exclusion criteria.</li> <li>Apply the outcomes of evidence review to refine the research question(s).</li> </ul>	Level 1	Level 2	Level 3

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
The elements (statistical, epidemiological, and operational) of clinical and translational study design.	<ul style="list-style-type: none"> <li>• Describe the characteristics of the key phases of research translation.</li> <li>• Explain how incorporating health economics and process evaluation into study design enhances the utility of the study.</li> <li>• Demonstrate understanding of the importance of statistics in clinical trial design.</li> <li>• Articulate how other types of research can inform study design.</li> </ul>	Level 1	Level 2	Level 3
Design of a clinical trial that demonstrates the integration of a robust protocol.	<ul style="list-style-type: none"> <li>• Identify the expertise that will be required in a multi-disciplinary research team.</li> <li>• Explain the concept of clinical equipoise.</li> <li>• Articulate the epidemiological and statistical principles of study design.</li> <li>• Explain the importance of consumer input into clinical trial design, conduct and dissemination of results, including the demands placed on participants.</li> <li>• Explain the importance of engaging a broad range of stakeholders, including consumers, in protocol development and discussions around study quality.</li> <li>• Describe the reasons why and when a study may have to close and what the requirements are for this to occur.</li> <li>• Explain the need for and mechanisms to achieve blinding and randomisation in a clinical trial.</li> <li>• Compare and contrast the relationship between study design and the outcome measures, and analysis and interpretation of results and data.</li> <li>• Explain why inclusion and exclusion criteria are included in a clinical protocol.</li> <li>• Explain the importance of clinical trial registration.</li> <li>• Choose study end-points that facilitate study feasibility while maximising the value to clinicians and policy-makers.</li> <li>• Demonstrate an understanding of the content of a Clinical Trial Development Plan.</li> <li>• Understand the purpose for which a trial is being conducted and maximising the value of that information to improve healthcare outcomes.</li> </ul>	Level 1	Level 2	Level 3

## Broad area

Study design - Ethical and participant safety considerations

## Summary

Encompasses care of participants, aspects of human participant protection, and safety in the conduct of a clinical trial.

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
<p>The principles of ethical conduct in human research as articulated in the <i>National Statement on Ethical Conduct in Human Research, 2007</i> (the National Statement) and the <i>Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research</i>.</p>	<ul style="list-style-type: none"> <li>• Describe the principles of justice, beneficence, respect and scientific merit and integrity in respect to clinical trials and how these principles might apply to different participant groups that may be part of the trial.</li> <li>• Explain the evolution of the requirement for informed consent from research participants.</li> <li>• Understand the principles and content of the key documents ensuring the protection of human participants in clinical research, e.g. Participant Information and Consent Forms (PICFs) and the Human Research Ethics Application (HREA).</li> <li>• Evaluate the requirements for human subject protections in different jurisdictions and international settings, and how they might be implemented throughout all phases of a clinical study.</li> <li>• Demonstrate an understanding of the <i>Privacy Act 1988</i> as it relates to human participation in trials.</li> <li>• Compare the differences between the types of consent and how they may be obtained in regards to relevant jurisdictional legislation.</li> <li>• Explain the ethical issues involved with engaging specific populations or participant groups in a clinical trial including medically vulnerable, culturally diverse populations.</li> <li>• Compare the principles of balancing risk and benefit through selection and management of clinical trial subjects.</li> <li>• Identify and explain strategies for risk minimisation to populations involved in the trial, including minimising participant burden.</li> <li>• Demonstrate the capability to conduct an informed consent discussion in accordance with the National Statement.</li> </ul>	Level 1	Level 2	Level 3

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
The principles of ethical conduct in human research as articulated in the <i>National Statement on Ethical Conduct in Human Research, 2007</i> (the National Statement) and the <i>Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research</i> (continued).	<ul style="list-style-type: none"> <li>• Understand distinction between responsibilities of healthcare system for provision of care and responsibilities of the trial and how this nexus is managed.</li> <li>• Describe how therapeutic misconception might arise and how it can be managed.</li> <li>• Understand the circumstances in which re-consent would be required.</li> <li>• Understand the impact of historical events on Aboriginal and Torres Strait Islander health and health service access, and the implications of these events on building trust and relationships with individuals, families and communities in health practice.</li> <li>• Identify current demographic, health indicators and statistical trends for Aboriginal and Torres Strait Islander peoples and compare these to trends for non-Indigenous peoples in Australia over time.</li> </ul>	Level 1	Level 2	Level 3
The organisation of Human Research Ethics Committees (HRECs) in Australia.	<ul style="list-style-type: none"> <li>• Understand how to identify the correct HREC approval to be obtained for all clinical trials, e.g. mutual acceptance models.</li> </ul>	Level 1	Level 2	Level 3
Considerations in the collection of human tissues samples and biospecimens, including ongoing privacy.	<ul style="list-style-type: none"> <li>• Identify ways in which biospecimen collection can add value to clinical trial outcomes, including genetic material.</li> <li>• Understand the importance of considering future usage of samples collected during the trial (including genetic material) or routine tissue banking, and how communication with participants and protection of privacy will be managed.</li> </ul>	Level 1	Level 2	Level 3
Conflicts of interest associated with the trial.	<ul style="list-style-type: none"> <li>• Define how real or perceived conflicts of interest can arise and the potential impact they might have on a clinical trial.</li> <li>• Describe how research sponsorship or collaboration between industry, academic institutions and other sponsors might influence design, conduct and analysis of results.</li> <li>• Identify and implement procedures for the prevention or management of the ethical and professional conflicts of interest that are associated with the conduct of clinical research.</li> </ul>	Level 1	Level 2	Level 3
The legislative framework in Australia and its impact on study design and execution.	<ul style="list-style-type: none"> <li>• Explain how the legislative framework supports the development, registration and subsidisation of medicines, techniques, interventions, devices and biologics; and ensures their safety, efficacy and quality.</li> </ul>	Level 1	Level 2	Level 3

## Broad area

Study initiation, conduct and data collection - Feasibility assessment and study initiation

## Summary

Encompasses content required to initiate a study at the site level. Includes governance approval and authorisation.

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
The components and importance of a thorough feasibility assessment at the trial, sponsor and site level.	<ul style="list-style-type: none"> <li>Identify how trial design decisions can impact the feasibility of the trial.</li> <li>Identify the key stakeholders relating to clinical trial feasibility.</li> <li>Explain the key factors relating to feasibility of recruitment of participants at a site into a particular study.</li> <li>Explain the importance of early engagement with clinical service providers, clinical staff and other key stakeholders on the success of a study.</li> <li>Explain the importance of a robust method for deciding appropriate numbers of clinical trial participants and resources.</li> <li>Identify the core components of a clinical trial feasibility assessment.</li> <li>Explain why clinical trials may not be completed on time and on target in regards to recruitment.</li> </ul>	Level 2	Level 2	Level 3
Mechanisms and processes used by a site to initiate a study.	<ul style="list-style-type: none"> <li>Describe the process for undertaking and obtaining site assessment and authorisation, ethics review and seeking agreements from relevant departments.</li> <li>Describe the considerations/issues that will determine whether or not to sponsor, initiate, supervise or participate in a clinical trial.</li> <li>Describe the role of site governance processes (<b>Site Specific Assessment</b>) in relation to insurance, budgets, contracts, radiation safety, indemnity etc.</li> </ul>	Level 2	Level 2	Level 3

## Broad area

Study initiation, conduct and data collection - Clinical trials conduct

## Summary

Encompasses International Committee on Harmonization – Good Clinical Practice compliance.

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
Requirements of International Committee on Harmonization guidelines for Good Clinical Practice (GCP).	<ul style="list-style-type: none"> <li>Describe the roles and responsibilities of the clinical investigation team as defined by GCP guidelines including delegations.</li> <li>Evaluate the design, conduct and documentation of clinical trials, as required for compliance with GCP guidelines that are relevant to investigator-initiated clinical trials.</li> <li>Be aware of the regulations and guidelines of global and major national regulatory bodies relating to the conduct of clinical trials.</li> <li>Describe appropriate control, storage, dispensing and disposal of investigational products.</li> </ul>	Level 1	Level 2	Level 3
The conduct and management of clinical trials within the context of a Clinical Development Plan.	<ul style="list-style-type: none"> <li>Demonstrate understanding of what is required in a Clinical Development Plan for the management and implementation of a clinical trial.</li> <li>Describe how clinical trials are monitored and how risk-based monitoring may be appropriate for academic clinical trials.</li> </ul>	Level 2	Level 2	Level 3
Professional guidelines and codes of research conduct that apply to the conduct of clinical research.	<ul style="list-style-type: none"> <li>Demonstrate a detailed understanding of the <i>Australian Code for the Responsible Conduct of Research, 2007</i> (the Code) including requirements for the management and investigation of potential breaches of the Code/ research misconduct.</li> </ul>	Level 2	Level 2	Level 3

## Broad area

Study initiation, conduct and data collection - Study and site management

## Summary

Encompasses content required at the site level to run a study, including financial and personnel aspects. Includes site and study operations.

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
The roles and processes for monitoring of the study.	<ul style="list-style-type: none"> <li>• Demonstrate ability to apply agreed trial processes in actively monitoring the study.</li> <li>• Demonstrate understanding of processes for protocol amendments.</li> </ul>	Level 2	Level 2	Level 3
Reporting requirements of global regulatory bodies relating to clinical trial conduct and how Therapeutic Goods Administration (TGA) reporting requirements apply to academic clinical trials.	<ul style="list-style-type: none"> <li>• Demonstrate an understanding of the reporting requirements of global regulatory bodies relating to clinical trial conduct.</li> <li>• Understanding of TGA requirements and how they apply to academic clinical trials, e.g. Clinical Trial Notification (CTN), Clinical Trial Exemption (CTX).</li> </ul>	Level 2	Level 2	Level 3
Methods by which safety issues are identified and managed during the development phases of clinical research.	<ul style="list-style-type: none"> <li>• Describe the various methods to identify and manage safety issues during the development phases of clinical research.</li> </ul>	Level 2	Level 2	Level 3
Safety monitoring and reporting requirements of regulatory agencies.	<ul style="list-style-type: none"> <li>• Apply the safety monitoring and reporting requirements for both Australian and multinational clinical trials.</li> <li>• Ability to differentiate between types of adverse events (AEs) that occur during clinical trials, understand the identification process for AEs, and describe the reporting requirements to HRECs, sponsors and regulatory authorities.</li> <li>• Demonstrate understanding of role and authority of the Data Safety Monitoring Board for the trial.</li> </ul>	Level 1	Level 2	Level 3

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
The roles of different parties in the clinical trial process.	<ul style="list-style-type: none"> <li>Describe the roles of sponsors, investigators, HRECs, site staff, regulators and administrators in the approval and conduct of a clinical trial.</li> <li>Understand the contemporary role of Aboriginal and Torres Strait Islander health professionals, organisations and communities in delivering culturally safe health care to Aboriginal and Torres Strait Islander clients.</li> </ul>	Level 2	Level 2	Level 3
The roles and purpose of clinical trial audits.	<ul style="list-style-type: none"> <li>Describe the need for fidelity to protocol, particularly in behavioural interventions.</li> <li>Describe the importance of accurate monitoring and reporting.</li> </ul>	Level 2	Level 2	Level 3
The timeline involved, financial and cross-disciplinary personnel resources necessary to conduct the study.	<ul style="list-style-type: none"> <li>Understand the human resources required at a site level.</li> <li>Understand how sites decide whether the study meets with their organisational requirements.</li> <li>Utilise elements of project management related to the organisation and ability of the study site to manage patient recruitment, complete procedures, and track progress.</li> </ul>	Level 2	Level 2	Level 3
Management concepts and effective training methods to manage risk and improve quality in the conduct of the study.	<ul style="list-style-type: none"> <li>Describe the relevance and importance of quality control mechanisms that may be adopted to ensure the fidelity of trials, including adherence to protocol.</li> </ul>	Level 2	Level 2	Level 3
Legal responsibilities, issues, liabilities and accountabilities that are involved in the conduct of a clinical trial.	<ul style="list-style-type: none"> <li>Identify and interpret legal responsibilities in relation to management of clinical trials.</li> <li>Demonstrate an understanding of state or territories specific laws and regulations in relation to research governance and ethics.</li> <li>Explain the importance of insurance and indemnity for trial sites.</li> </ul>	Level 1	Level 2	Level 3
Specific procedural documentation in line with oversight requirements of PIs, institutional sponsors and regulatory authorities related to the conduct of an institutionally sponsored clinical trial.	<ul style="list-style-type: none"> <li>Demonstrate a detailed knowledge of standard operating procedures.</li> <li>Ability to draft standard operating procedures and protocols of academic clinical trials.</li> </ul>	Level 2	Level 2	Level 3
The significance of quality assurance systems and how Standard Operating Procedures (SOPs) are used to guide them.	<ul style="list-style-type: none"> <li>Describe the need for a culture that rewards critical thinking and open dialogue about quality that goes beyond sole reliance on tools and checklists.</li> <li>Describe activities that are essential for the credibility of the study outcomes.</li> <li>Describe why quality factors must be prospectively identified and periodically reviewed.</li> <li>Describe the need for and value of SOPs in clinical trial activities.</li> </ul>	Level 1	Level 2	Level 3

## Broad area

Study initiation, conduct and data collection - Leadership, teamwork and communication

## Summary

Encompasses the principles and practice of leadership. Encompasses all elements of communication within the site and between the site, network members, regulators and the community.

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
Strategies to build relationships and appropriate communication between sponsor, networks and clinical research sites.	<ul style="list-style-type: none"> <li>Describe the role of key stakeholders involved in the conduct and oversight of clinical trials, including sponsors (whether commercial or non-commercial).</li> <li>Use effective strategies to work collaboratively with stakeholders including sponsors and research networks.</li> </ul>	Level 1	Level 2	Level 3
The principles and practices of leadership, management, and mentorship, and apply them within the working environment.	<ul style="list-style-type: none"> <li>Describe strategies to ensure team awareness and knowledge of strategies to minimise bullying and harassment in the workplace.</li> <li>Develop and implement plans for supervision of research students and trainees.</li> </ul>	Level 1	Level 2	Level 3
The benefits of workplace diversity in the design and conduct of clinical research.	<ul style="list-style-type: none"> <li>Value and respect workplace diversity and inclusiveness.</li> </ul>	Level 1	Level 2	Level 3
Methods necessary to work effectively with multidisciplinary and inter-professional research teams.	<ul style="list-style-type: none"> <li>Ability to work as a member of a multidisciplinary team.</li> <li>Understand how own role and the role of others' complement and fit within a diverse clinical trials team.</li> </ul>	Level 2	Level 3	Level 3
The content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community.	<ul style="list-style-type: none"> <li>Understand the importance of disseminating and publishing research results in a timely fashion.</li> <li>Understand the important contribution of clear and concise (plain English) language to the effectiveness of communication.</li> </ul>	Level 1	Level 2	Level 3

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
The content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community (continued).	<ul style="list-style-type: none"> <li>• Describe strategies to ensure timely publication.</li> <li>• Describe the component parts of a traditional scientific publication.</li> <li>• Understand the principles of authorship and the criteria for being included as an author on a research paper.</li> <li>• Be aware of international guidelines (e.g. CONSORT) for reporting research.</li> <li>• Demonstrate a commitment to depositing research data in an Open Access repository, in accordance with funding body requirements.</li> <li>• Understand the importance of disseminating results in plain English to consumer/patient groups and not-for-profit organisations.</li> </ul>	Level 1	Level 2	Level 3
Risk management and complaints.	<ul style="list-style-type: none"> <li>• Demonstrate an understanding of systems to manage risks to participants, staff and to the research process and to detect risk-related events.</li> <li>• Ensure systems are in place to manage complaints from research participants.</li> </ul>	Level 1	Level 2	Level 3

## Broad area

Study initiation, conduct and data collection - Data management, informatics and privacy legislation

## Summary

Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control or biospecimens. Includes the concept of a locked database and site closure.

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
The relevance and importance that data, biostatistics and informatics play in biomedical and public health research.	<ul style="list-style-type: none"> <li>Develop statistical plans for data analysis (e.g. before lock of database occurs).</li> <li>Understand how publishing protocols and statistical analysis plans can enhance confidence in the reported results.</li> <li>Understand the concept of data linkage and the potential for its contribution to clinical research, especially with respect to issues around 'big data'.</li> </ul>	Level 1	Level 2	Level 3
Analyse study results with an understanding of therapeutic and comparative effectiveness.	<ul style="list-style-type: none"> <li>Apply statistics knowledge to evaluate study results in the context of the intervention.</li> <li>Apply comparative effectiveness research thinking when analysing results and comparing trial intervention with existing treatment or practice.</li> </ul>	Level 1	Level 2	Level 3
The principles of data integrity and management throughout a clinical trial.	<ul style="list-style-type: none"> <li>Understand the need for, and describe the contents of, a data management plan including quality assurance.</li> <li>Be aware of the processes for preparing and implementing plans to un-blind/unmask.</li> </ul>	Level 2	Level 2	Level 3
The process of electronic data capture and the importance of information technology in data collection and queries, capture, management and source data verification.	<ul style="list-style-type: none"> <li>Understand the concept and use of electronic data management systems.</li> <li>Understand the need for source data verification.</li> <li>Understand the need for data integrity and how it contributes to the robustness of clinical trial results.</li> <li>Describe the GCP guideline requirements for data correction and queries.</li> <li>Demonstrate knowledge of the different databases required for collecting clinical trials data.</li> <li>Understand processes for preparation of database locking.</li> </ul>	Level 2	Level 2	Level 3

Element	Criteria to demonstrate competence	Site Staff	Site PI	Lead PI
Australian privacy legislation and the use of data.	<ul style="list-style-type: none"> <li>• Demonstrate a familiarity with relevant guidelines issued under Section 95, 95(A) and 95(AA) of the <i>Privacy Act 1988</i>.</li> <li>• Understand the mechanisms for privacy protection of data and study materials, e.g. de-identification.</li> </ul>	Level 2	Level 2	Level 3
Elements associated with closing a study at a site.	<ul style="list-style-type: none"> <li>• Describe the reporting requirements for study site closeout, including governance and HREC.</li> <li>• Understand the importance of ensuring appropriate patient communication and follow up.</li> <li>• Verify that study procedures have been completed.</li> <li>• Understand the importance of data verification.</li> <li>• Explain the importance of safe destruction of study drug.</li> <li>• Explain the importance of archiving trial records and processes to maintain long term storage and security of trial materials.</li> </ul>	Level 2	Level 2	Level 3

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## Glossary

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### Australian Code for the Responsible Conduct of Research

The *Australian Code for the Responsible Conduct of Research, 2007* ([the Code](#)) guides institutions and researchers in responsible research practices and promotes research integrity. It assists institutions in developing their own policies and processes for the investigation of allegations of research misconduct. The Code is developed jointly by the National Health and Medical Research Council, Australian Research Council and Universities Australia.

### Clinical trial phase

Many clinical trials to develop new interventions are conducted in phases. In the early phases, the new intervention is tested in a small number of participants to assess safety and effectiveness. If the intervention is promising, it may move to later phases of testing where the number of participants is increased to collect more information on effectiveness and possible side effects.

Clinical trials of biomedical interventions typically proceed through four phases.

#### **Phase I clinical trial**

Phase I clinical trials are done to test a new biomedical intervention for the first time in a small group of people (e.g. 20-80) to evaluate safety (e.g. to determine a safe dosage range and identify side effects).

#### **Phase II clinical trial**

Phase II clinical trials are done to study an intervention in a larger group of people (several hundred) to determine efficacy (that is, whether it works as intended) and to further evaluate its safety.

#### **Phase III clinical trial**

Phase III studies are done to study the efficacy of an intervention in large groups of trial participants (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions (or to non-interventional standard care). Phase III studies are also used to monitor adverse effects and to collect information that will allow the intervention to be used safely.

#### **Phase IV clinical trial**

Phase IV studies are done after an intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use over longer periods of time. They may also be used to investigate the potential use of the intervention in a different condition, or in combination with other therapies.

\*[Australianclinicaltrials.gov.au](http://australianclinicaltrials.gov.au).

#### **Other clinical trials**

Researchers may also conduct **exploratory studies**, sometimes referred to as 'Phase 0 trials' or 'pilot studies'. These come before Phase I trials and are used to test how the body responds to an experimental drug. In these studies, small doses of the new drug are given once or for a short time to a very limited number of people.

Clinical trials of diagnostic tests are sometimes divided into exploratory phases, challenge phases and advanced phases to see how effective and how accurate the tests are.

Medical devices, surgical techniques and other clinical procedures (such as radiation, imaging techniques or diagnostic tests) can also be tested in a phased manner; however the typology of these phases may be different to that used for clinical drug trials.

## Database lock

A term of art for an action taken to prevent further changes to the trial database in a clinical trial. A database is locked after review, query resolution and a determination that it is ready for analysis.

(Source: Segen's Medical Dictionary. S.v. "database lock." Retrieved February 8 2017 from <http://medical-dictionary.thefreedictionary.com/database+lock>)

## Data Safety Monitoring Board (DSMB)

A DSMB is a multidisciplinary group established by the trial sponsor to review, at intervals, accumulating trial data, to monitor the progress of a clinical trial. Its role is to provide advice on data integrity, safety and/or trial conduct issues by making recommendations to the sponsor, or their Trial Steering Committee, on whether to continue, modify or stop a trial for safety or ethical reasons. DSMBs go by a variety of other names, including Data Monitoring Committee, Trial Monitoring Committee and Data Monitoring and Ethics Committee.

For more information on DSMBs, see <https://www.nhmrc.gov.au/guidelines-publications/eh59>.

## Governance review and authorisation

A process used by an organisation for the oversight, assessment, authorisation and monitoring of research conducted at one or more of its sites or a site under its auspices.

Research cannot commence at a site until the governance review process is completed and the research has received the necessary authorisation.

## Human Research Ethics Committee (HREC)

Human Research Ethics Committees (HRECs) play a central role in the Australian system of ethical oversight of research involving humans. HRECs review research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

Internationally, HRECs are known by a variety of names, including Institutional Review Board (IRB) and Institutional Ethics Committee (IEC).

A list of all HRECs 'registered' with NHMRC can be found at:

<https://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs>

## International Committee on Harmonization – Good Clinical Practice (ICH-E6 GCP)

The ICH's Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials of medical interventions that involve the participation of human beings. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

GCP has been largely adopted in Australia by the Therapeutic Goods Administration (TGA); however, the TGA has recognised that some elements are, by necessity, overridden by the National Statement (and therefore not adopted) and that others require explanation in terms of 'local regulatory requirements'. Compliance with GCP is a condition for all trials conducted under the Clinical Trials Notification (CTN) or Clinical Trials Exemption (CTX) schemes.

The complete text of the 1996 ICH-E6 GCP document is available at:

[http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6/E6\\_R1\\_Guideline.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf)

A proposed amendment to ICH-E6 GCP was published in 2016 and can be found at:

[http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6/E6\\_R2\\_Step\\_4\\_2016\\_1109.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step_4_2016_1109.pdf)

In February 2018, the TGA issued a revised version of the GCP with TGA annotations incorporating the 2016 amendment. This can be found at:

<https://www.tga.gov.au/publication/note-guidance-good-clinical-practice>

### *National Statement on Ethical Conduct in Human Research, 2007*

The *National Statement on Ethical Conduct in Human Research, 2007* (National Statement) consists of a series of guidelines made in accordance with the *National Health and Medical Research Council Act 1992*. The purpose of the National Statement is to promote ethically appropriate human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community.

The National Statement is therefore designed to clarify the responsibilities of:

- institutions and researchers for the ethical design, conduct and dissemination of results of human research; and
- review bodies in the ethical review of research.

The National Statement is jointly authored by the National Health and Medical Research Council, Australian Research Council and Universities Australia.

The National Statement can be found at:

<https://www.nhmrc.gov.au/guidelines-publications/e72>

## Australian privacy legislation

The Australian *Privacy Act 1988* (Privacy Act) is a federal law that regulates how personal information is handled. The Privacy Act defines personal information as:

“...information or an opinion, whether true or not, and whether recorded in a material form or not, about an identified individual, or an individual who is reasonably identifiable”.<sup>2</sup>

Common examples are an individual's name, signature, address, telephone number, date of birth, medical records or bank account details, and commentary or opinion about a person.

The Privacy Act includes thirteen *Australian Privacy Principles* (APPs), which apply to some private sector organisations, as well as most Australian and Norfolk Island government agencies. These are collectively referred to as ‘APP entities’.

Most states and territories have their own privacy legislation that apply to data held by state and territory government agencies as well as by some public sector organisations (such as universities). Some jurisdictions also have medical record legislation that protects health information contained in a health record held by a health practitioner (e.g. general practitioners) and permits disclosure of health information to patients and, in some instances, researchers.

Access to some nationally held records – for example, those held by the Electoral Commissioner and Australian Institute of Health and Welfare – may be governed by different legislation.

## Site specific assessment

A process that assesses research against institutional requirements and any applicable jurisdictional requirements (including legal obligations). The outcome of a site specific assessment is site authorisation: a determination by an organisation that a research project to be conducted at one or more of its sites or under its auspices satisfies organisational requirements and may commence at the site/s over which it exercises its authority.

## Systematic review

The purpose of a systematic literature review is to evaluate and interpret all available research evidence relevant to a particular question. In this approach, a concerted attempt is made to identify all relevant primary research, a standardised appraisal of study quality is made and the studies of acceptable quality are systematically (and sometimes quantitatively) synthesised. This differs from a traditional review in which previous work is described but not systematically identified, assessed for quality and synthesised.

For further information on the design and conduct of a systematic literature review see:

*How to Review the Evidence: Systematic Identification and Review of the Scientific Literature* (1999)  
[https://www.nhmrc.gov.au/\\_files\\_nhmrc/publications/attachments/cp65.pdf](https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cp65.pdf)

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<sup>2</sup> <https://www.legislation.gov.au/Details/C2014C00076>

## Therapeutic Goods Administration (TGA)

The TGA is Australia's regulatory authority for therapeutic goods. Under the *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations 1990*, the TGA carries out a range of assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard, with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.

## Therapeutic misconception

Therapeutic misconception is commonly understood as a clinical trial participant's 'belief that the purpose of a clinical trial is to benefit the individual patient rather than to gather data for the purpose of contributing to scientific knowledge.' (National Bioethics Advisory Committee, 2001).

Researchers must minimise the potential for therapeutic misconception by clearly explaining the nature and purpose of their research as part of the informed consent process. The National Bioethics Advisory Committee advises:

“It is important to distinguish the confusion that arises from the therapeutic misconception from a related consideration. In the research setting, participants often receive beneficial clinical care. ... It is not a misconception to believe that participants probably will receive good clinical care during research. But it is a misconception to believe that the purpose of clinical trials is to administer treatment rather than to conduct research. Researchers should make clear to research participants, in the initial consent process and throughout the study, which activities are elements of research and which are elements of clinical care”.<sup>3</sup>

## Translational research phases

Translation research has been described as 'moving knowledge gained from the basic sciences to its application in clinical and community settings. This concept is often summarized by the phrases "bench-to-bedside" and "bedside-to-community" research.' It includes:

- the process of making discoveries in the research laboratory or in preclinical studies that will have an impact on human health and may lead to the development of studies in humans,
- the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans, and
- research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

(<https://www.iths.org/investigators/definitions/definitions-of-clinical-and-translational-research/>)

In Australia, further information on translational research phases can be found at:  
<http://www.tcrn.unsw.edu.au/translational-research-definitions>.

3 <https://bioethicsarchive.georgetown.edu/nbac/clinical/Vol1.pdf>

## Values and Ethics Guidelines

*Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (Values and Ethics) provides guidance to researchers and Human Research Ethics Committees (HRECs) on the complex considerations necessary in the conception, design and conduct of appropriate research in Aboriginal and Torres Strait Islander communities.

*Keeping Research on Track* is the translation of Values and Ethics into concrete expectations, actions and outcomes for all involved in research.

