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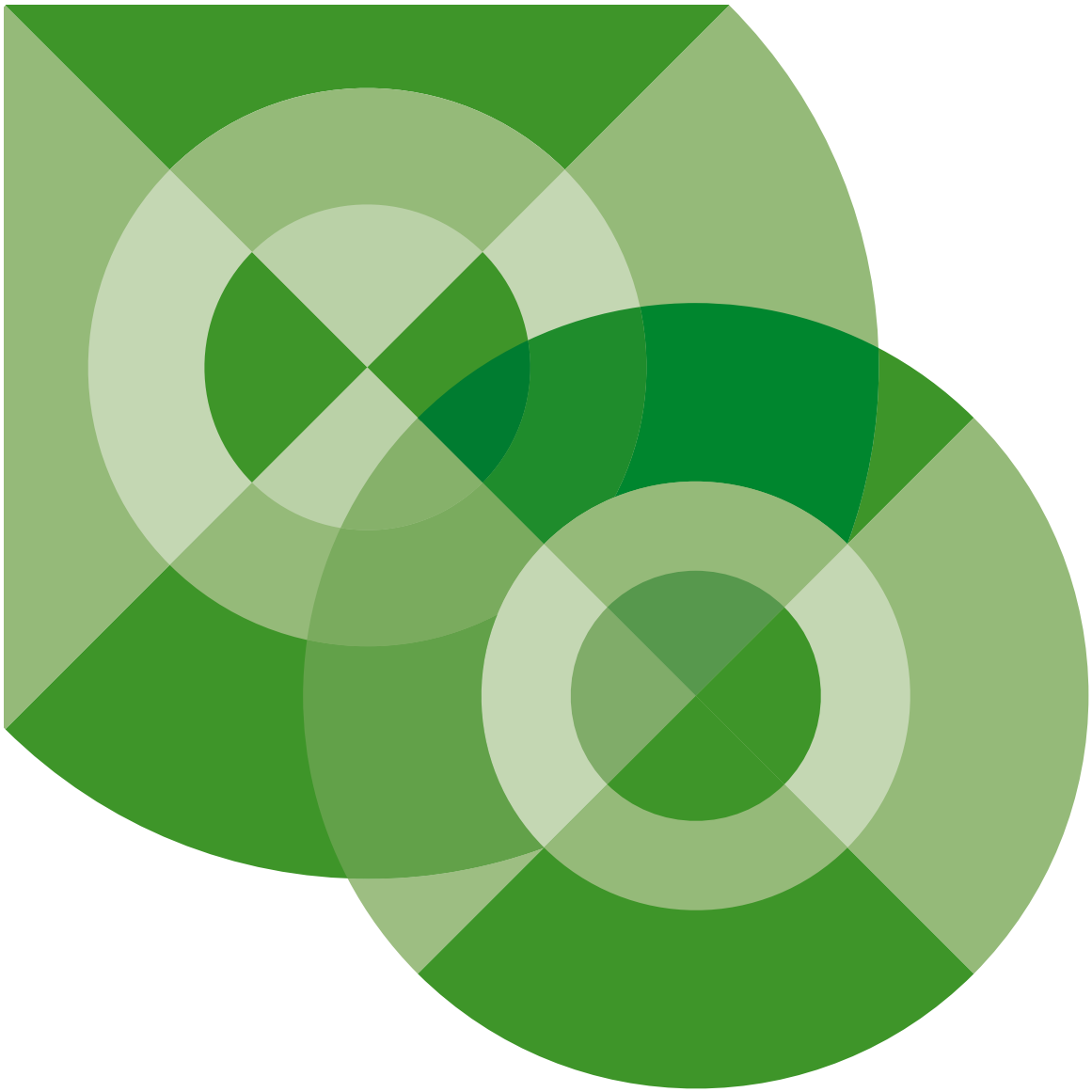

The National Clinical Trials Governance Framework

Mapping Exercise Report

Australian Government
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Contents

Key findings 2

Executive summary 4

Section 1 6

Introduction 6
Background 6
Methodology 7
Analysis 8

Section 2 9

National regulation, legislation and initiatives 9
National initiatives 15
Private and not-for-profit sector initiatives 17

Section 3 20

Discussion elements 20

Section 4 23

Expectations of the national Clinical Trials Governance Framework 23
Application of the Governance Framework 23

Section 5 25

Jurisdictional legislation, policies and initiatives 25

Summary 43

Appendix 1 44

Appendix 2 45

Appendix 3 57

List of abbreviations 58

References and Endnotes 60

Key findings

In Australia, a series of legislative, regulatory and policy frameworks are provided at the national, state and territory departments of health, private sector health providers and universities for undertaking clinical trials. Most state and territory departments of health have a research office[1] with localised frameworks, policies and standards for the conduct of clinical trials including:

- Forms and guidance material specific to obtaining Human Research Ethics Committee (HREC) approval for a clinical trial
- Forms and guidance materials specific to the functions of the research governance office.

A series of national initiatives intended to contribute to the national harmonisation and streamlining of clinical trial procedural and operational processes have been implemented at the state/territory and local level with varying degrees of success. These initiatives include:

- National Mutual Acceptance (NMA) scheme
- Single point of contact or valet service for trial sponsors
- National Aggregate Statistics (NAS).

The Australian Department of Health is developing a national clinical trials platform, the 'clinical trials front door'. This initiative along with the *Encouraging More Clinical Trials in Australia* budget measure ($7 million) is supported by all jurisdictions to drive local improvement in the clinical trial operating environment. Additionally, a series of specialist national groups provide guidance across the clinical trials sector including:

- The Australian Clinical Trials Alliance (ACTA), which plays a key role in networking across the research sector, fostering collaboration between co-operative clinical trial groups and clinicians to provide expertise and infrastructure support to clinical trial investigators
- The Advanced Health Research Translation Centres (AHRTCs), building collaborations across the university, health and research
- The Clinical Trials Project Reference Group (CTPRG), representing all jurisdictions is recognised as playing a key role in the development of processes to streamline HREC review and approval
- The Clinical Trials Forum, with members from jurisdictions, government, industry and the private sector is recognised for enabling the sector to identify issues, exchange information and engage in collaborative problem solving with a view to reducing duplication and improving the clinical trials environment. The Forum has a number of initiatives including acceptance of the Medicines Australia Clinical Trial Agreement across South Eastern Border States (SEBS).

Several jurisdictions have implemented new technology infrastructure and work flow systems. There was a perception that this investment impeded a national approach to managing workflow and national reporting on operational performance metrics. However, opportunities for connectivity between jurisdictional platforms are currently being explored through work by the Australian Government to develop a concept for a potential national clinical trials front door in collaboration with all jurisdictions.

Jurisdictions are also investing in roles such as the National Health and Medical Research Council (NHMRC) recommended Clinical Trial Liaison Officer. Although not uniformly implemented, the positive impact of the role of the Clinical Trial Liaison Officer and the NHMRC Good Practice Process was recognised as improving local clinical trial site operations.

None the less, the mapping exercise has found variable uptake of good practice processes across the private and public sectors, is impacted by:

- The absence of nationally consistent standard operating procedures leading to inconsistent work-flow arrangements for trial sites
- The lack of a national approach to managing workflow and national reporting on operational performance metrics. Several jurisdictions have implemented new technology infrastructure and work flow systems and it is envisaged jurisdictional platforms will connect as intra-operable systems through the Australian Government Department of Health national platform, the 'clinical trials front-door', when it is developed
- The absence of a consistently applied definition of 'governance' and confusion regarding the role and function of the research governance office by trial sponsors, investigators and site staff
- The lack of a uniform approach to site staff training and certification, limiting a health service's capacity to engage a skilled and reliable workforce.

As a consequence, the National Clinical Governance Framework and the accreditation of health services and sites conducting clinical trials is greatly anticipated by key stakeholders across the clinical trials sector.

Executive summary

Stakeholders across the public and private health sectors agree on the benefits to patients of clinical trials and the need for clinical trials to be integrated into clinical care. The mapping exercise builds upon the findings from the international and national literature review to describe existing legislation and policies relating to the governance of clinical trials in Australia, and considers the work already undertaken by national and jurisdictional agencies to improve the clinical trial operating environment. The compendium of national and jurisdictional guidance material, updated with findings from the literature review and mapping exercise is provided at Appendix 2. Additionally, interviews with key stakeholder groups have provided insights into the efforts underway to revitalise the sector more broadly.

Although there are national initiatives underway to minimise administrative variation, interview participants identified significant process and policy variation between jurisdictions, as negatively impacting the clinical trial pre-approval process. Several interview participants were of the view these variations diminish Australia's appeal as a destination to conduct clinical trials, and that fewer clinical trials were being conducted in Australia as a result. Legislative variation was less frequently identified as an area of inefficiency, although there was limited awareness of how jurisdictional policies and processes aligned with national regulation, legislation and guidance material. Participants across all groups attributed the introduction of the NMA and the NHMRC system for registering HRECs to improved HREC review and approval time-frames in the public sector. Participants agreed an audit of the quality of HREC review is needed to provide assurance of the consistency of HREC review, as the lack of acceptance of the NMA across the public, private and university sectors was considered the largest single barrier to timely and streamlined HREC review and approval. Participants recommended the expansion of the NMA to the private and not-for-profit sectors and universities, and suggested mutual recognition of non-public HREC approvals across the public sector should be considered.

The term 'research governance' and its distinction from ethical review was frequently misunderstood, and confusion remains regarding the definition of 'governance' and, the role and function of the research governance office. Participants acknowledged that people employed in the research governance approval process continued to be unclear about their role, resulting in overlap and duplication in the local site governance review process. Participants commented that research governance, particularly the Site-Specific Assessment (SSA) processes, could benefit from the same focus ethical review has received. Jurisdictions identified issues related to the absence of a single national SSA form and application process, and the sequential rather than concurrent review of HREC and SSA. The frustration and inefficiency caused by numerous SSA application forms resonated across the private sector, where variation in the acceptability of the Medicines Australia Clinical Trial Research Agreement (CTRA) and insurance and indemnity requirements also delays the preapproval process.

Many participants reported that retaining a skilled and reliable workforce was an opportunity for improving efficiency. The lack of training, security of tenure and high staff turnover were identified as having a negative impact on the quality and effectiveness of trial conduct. Participants agreed these factors contributed to delays in all parts of the clinical trial process and were most apparent in trial start-up time frames and participant recruitment and retention rates.

Participants acknowledged the Australian Government Department of Health initiative to provide $1.3 Billion over ten years from 2017-18 for a *National Health and Medical Industry Growth Plan* to improve health outcomes and develop Australia as a global destination for medical sector jobs, research and clinical trials. This includes $248M for rare cancers and rare disease clinical trial programs.

The *Encouraging More Clinical Trials in Australia* budget measure ($7 million) in 2017 was considered a key funding driver for the sector and was supported for having incentivised a number of jurisdictional activities to improve the local clinical trial environment. Government funding for cancer clinical trials has been provided for more than a decade through the NSW Department of Health, Cancer Institute NSW to hospitals in NSW for the recruitment of patients to a portfolio of cooperative group or investigator initiated cancer clinical trials. Cancer Councils and non-profit agencies in other jurisdictions have contributed infrastructure support for cancer clinical trials elsewhere in Australia, however no other clinical area receives government funding to support clinical trial services. The Western Australia Department of Health is considering funding for clinical trials across all clinical groups, to be distributed based on trial units meeting specific targets in clinical trial operations. Detailed insights into jurisdictional initiatives are provided in Section 4 of this report, and discrete initiatives are highlighted below:

- The establishment of permanent clinical trial coordinator positions and a pool of trained and certified clinical trial staff
- The use of operational metrics for reporting operational performance at the level of the Chief Executive, Health Department, Director General and/or Secretary
- Consideration of implementing a block funding schedule into hospital funding agreements for clinical trials
- The implementation of expected time-frames for HREC and SSA approvals
- The implementation of performance targets for research governance approval in eight calendar days in the Australian Capital Territory (ACT) and, recommendations for HREC approval in 45 calendar days and research governance approval in 15 calendar days in other jurisdictions
- Standard operating procedures for HRECs
- The implementation of a competency framework for research governance officers
- The development of an early phase clinical trials framework
- The development of trial unit costing tools and budgetary guidance material including:
  - financial tracking spreadsheets and in-built calculations
  - income vs costs tracking documents
  - adopted the Independent Hospital Pricing Authority (IHPA) cost structures for clinical trials
  - costs for salaries, time, participant activity pricing and patient costs
- The trialling of a model for business unit support services including:
  - capturing data from the costing tool for activity based funding (fee for service)
- The development of clinical trial support units under the Council of Australian Governments Health Council revitalised clinical trials agenda and the *Encouraging more Clinical Trials in Australia* budget measure, with functions that include:
  - study start-up specialists
  - human resource and clinical trial manager
  - pool of coordinators
  - quality manager for post approval activities
- The pilot of a model for tele-clinical trials with national standard operating procedures
- The development and implementation of a Clinical Trials and Data Training Centre with:
  - central point of contact for clinical trial sponsors
  - on-line clinical practice training free to members
  - GCP training with four modules
- The development of standard operating procedures for the conduct of clinical trials by trial sites.

Interview participants broadly supported the development of a national Clinical Trials Governance Framework and standards against which sites could be assessed for accreditation. Standard development and accreditation was the preferred mechanism for a framework as participants suggested this could provide a consistent understanding of quality trial processes. Participants also agreed that the Clinical Trials Governance Framework needs to be relevant to all research settings including public, private and not-for-profit hospitals, universities and community health settings, for both commercially sponsored, and investigator-led studies. The lack of broad application across the research sector was thought to detract from its effectiveness and potentially cause greater confusion across the sector. The delineation of roles and responsibilities, workforce capability and the capacity to measure the effectiveness of clinical trial operations using agreed metrics and performance reporting were also considered essential elements of the framework.

Section 1

Introduction

The regulation of clinical trials is a complex process which operates at a number of levels under Australian Government and state and territory legislation. In addition, there are various responsibilities resting with trial sponsors, HRECs, the approving authority (institution) and investigators.[2] Most state and territory departments of health have a designated branch or office responsible for research. Their responsibilities encompass policy development, managing research grants and fellowships, establishing and overseeing research ethics and governance policies, and providing a central point of contact for researchers, research managers and study sponsors. However, the overall responsibility for the conduct of a clinical trial rests with investigators within hospital clinical departments.

The purpose of the mapping exercise is to build upon the findings from the literature review to identify existing policies and processes relating to the governance of clinical trials in Australia and, provide insights into the work underway in the public and private sector to improve their local clinical trial operating environments. Section 1 of this report provides the background and the methodology for undertaking the mapping exercise and, Section 2 provides an overview of national and jurisdictional regulation, legislation and guidance materials relating to the conduct of clinical trials. The overarching themes as they relate to elements of the clinical trial process as well as an overview of infrastructure investment and the context and scope of improvement activities is provided in Section 3. Section 4 provides the jurisdictional overview of current legislation, policies and improvement initiatives.

Background

Development of the National Clinical Trials Governance Framework (the Governance Framework), a flagship project for the Clinical Trials Project Reference Group (CTPRG), and a key element of the Council of Australian Governments Health Council agenda to revitalise the environment for clinical trials in Australia, was endorsed by all Health Ministers in March 2017. The purpose of the Governance Framework is to strengthen governance arrangements for clinical trials, and to provide clarity to governments, health services, hospital administrators, clinicians and others responsible for delivering clinical trials. An important aim is to reduce duplication and increase efficiency, cohesion and productivity across the clinical trials sector. The Governance Framework is due for completion in mid- 2019.

The Australian Commission of Safety and Quality in Health Care (the Commission) is under contract by the Australian Government Department of Health (the Department) to develop the Governance Framework as a first step toward accrediting health services undertaking clinical trials. The key deliverables of the project include a literature review and mapping exercise which will inform the development of the Governance Framework and high level implementation strategy. The Governance Framework will be underpinned by best practice principles which are consistent with existing national standards and regulations for the conduction of clinical trials in Australia. It will also align with the Commission's second edition National Safety and Quality Health Service Standards for hospital accreditation and National Model Clinical Governance Framework.

Methodology

The mapping exercise builds upon the findings from the international and national literature review to identify existing policies and procedures relating to the governance of clinical trials in Australia, and reflects upon the work already undertaken by national agencies including: the National Health and Medical Research Council (NHMRC) Good Practice Process; the Therapeutic Goods Administration (TGA) Note for Guidance on Good Clinical Practice; the revision of the Australian Code for the Responsible Conduct of Research (2015); National Mutual Acceptance (NMA) of Human Research Ethics approvals; the Clinical Trials Jurisdictional Working Group (CTJWG) Framework for National Aggregate Statistics and other jurisdictional initiatives.

The mapping exercise draws on information contained within these documents and key informant semi-structured interviews with members of the CTPRG and other stakeholders to capture insights into jurisdictional initiatives currently underway. Individuals representing the private health sector, jurisdictions, non-profit organisations, industry and academia were invited to participate in the interview process (Box 1).The Commission conducted interviews with jurisdictional representatives and contracted URBIS Pty Ltd to conduct and thematically analyse interview data from other stakeholder groups.

A discussion guide was developed, tested, and revised before the interviews were undertaken. The discussion guide, provided at Appendix 1, focussed on the following:

- Existing clinical trials policies and process
- Initiatives underway or in development to improve the local clinical trial environment
- Approaches to improve strategic planning for clinical trials in the public and private health sector
- Identifying resources, key agencies and networks and individuals that support the clinical trials sector
- Possible synergies between private and public health sector initiatives
- Factors to consider for developing a governance framework for clinical trials
- Components of a standard which would be required to measure efficient and effective clinical trial service provision.

Feedback was sought on current challenges associated with the conduct of clinical trials and capturing activities currently underway nationally or within jurisdictions to streamline clinical trials operations. Stakeholder perceptions on the development of a national Clinical Trials Governance Framework were also discussed. With the approval of the interview participant, interviews were audio-recorded and transcribed for analysis.

Box 1. Interview participant groups

- Australian Government Department of Health
- CTPRG members or jurisdictional representatives:
  - Australian Capital Territory
  - New South Wales
  - Victoria
  - Northern Territory
  - South Australia
  - Queensland
  - Western Australia
  - Tasmania (Paper provided by Dr Jodi Glading)
- PRAXIS Australia
- Australian Private Hospitals Association
- Catholic Health Australia
- Research Governance Officers
- Australian Institute of Aboriginal and Torres Strait Islander Studies (houses the Indigenous Caucus and the Research Advisory Committee)
- Aboriginal Health and Medical Research Council
- St John of God Hospital Services
- Independent Hospital Pricing Authority
- Hospital administrator
- Bellberry Human Research Ethics Committee (pending)
- Australian Clinical Trials Alliance
- Research nurse
- Consumer group
- NHMRC Clinical Trials Centre.

Analysis

A thematic analytical approach was taken with transcripts read iteratively to identify common themes and to develop a structure of perspectives from different stakeholder groups. Qualitative research does not seek to create a representative sample and responses are analysed for depth of insight rather than for breadth of participation. For this reason, a qualitative research approach does not allow for the number of participants holding a particular view on individual issues to be quantified. This approach provides an analysis of themes and perceptions among research participants rather than exact proportions of participants who hold a particular view.

In this report, qualitative research refers to data collected during the in-depth interviews with participants. Case studies have been provided throughout the report to illustrate the discussion findings. Findings from the grey literature identified by the Commission on current clinical trials governance processes within each jurisdiction are tabulated and provided in the literature review and findings from the analysis that dovetailed into national governing policies and processes were collated at the national and jurisdictional level (Table 1). Information collated through the key informant interviews were thematically analysed to describe governance processes at the research institute/site level, organisation and/or jurisdictional level.

Table 1: Discussion guide elements and sub-elements

ELEMENT	SUB-ELEMENT	
National and jurisdictional level	**Organisations**	Health departments
		Other relevant agencies
	Research policies and process documents	Jurisdictional policies relating to research conduct
		Other policies relevant to governing clinical trials
		Policies and processes in the private sector
		Process documents supporting trial oversight and activity
	Financial management and capability	Capability (workforce training, expertise and networks)
		Funding incentives
		Fee policies and activity costing for commercially sponsored trials
Data and infrastructure	**IT and other infrastructure**	Information systems
		Other infrastructure
	Metrics and reporting	Operational metrics relating to clinical trials and method of data capture
		Reporting requirements
Legal matters	**Legislative requirements**	Privacy laws
		Regulation and legislation
		Other relevant legislation
		Consumer engagement policies
		Data, storage and archiving policies
	Contracts and agreements	Confidentiality agreements
		Clinical trial research agreements
		Indemnity and insurance requirements
Ethics		National HREC policy documents
		Jurisdictional procedures for HRECs
		Risk assessment processes
		National Mutual Acceptance Scheme
		Supporting HREC policies and processes
Site-specific assessment		Role and function of the RGO
		Forms and processes

Section 2

National regulation, legislation and initiatives

The national legislative framework and policies were provided in detail in the literature review and are highlighted in this report to provide the context for the discussion of themes and insights gained through the interview process. The changing landscape of clinical trials in Australia is also described, in the background of initiatives underway across the private, non-profit and public sectors to streamline administrative processes and to grow the volume of clinical trials being conducted nationally. Below is an overview of regulation, legislation, policies, jurisdictional health departments and a discussion of improvement initiatives underway within jurisdictions and the private and non-profit sectors.

Most jurisdictional health departments have frameworks, policies and guidance material that apply to the conduct of clinical trials, and most state and territory departments of health have a designated branch or office responsible for research as listed below. Their responsibilities encompass policy development, managing research grants and fellowships, establishing and overseeing research ethics and governance policies, and providing a central point of contact for researchers, research managers and study sponsors:

- New South Wales (NSW) Ministry of Health – Office for Health and Medical Research (OHMR)
- Queensland Health Department – Health Innovation, Investment and Research Office (HIRO) which sits within the Office of the Director-General
- Victorian Department of Health and Human Services – Centre for Evaluation and Research and Health
- South Australia (SA) Health – Office for Research
- Western Australia (WA) Department of Health – The Research Development Unit
- Australian Capital Territory (ACT) Health – Office of Research
- Northern Territory – no specific office
- Tasmanian Department of Health – Research Governance Unit.

The exceptions are Tasmania and the Northern Territory. The Department of Health in Tasmania has contracted the University of Tasmania (UTAS) to provide the functions of the health and medical research office. The University of Tasmania through the UTAS Research Division and the UTAS Research Integrity and Ethics Unit, provide the functions of the HREC and research governance. In the Northern Territory the research office functions are provided two offices; the Menzies School of Health Research with the Top End HREC, and the Central Australian HREC which operates under the auspices of the Centre for Remote Health, and considers applications for all human research being conducted for research undertaken in the adjoining tristate areas (AP Lands of South Australia or the Ngaanyatjarra lands of Western Australia). Ethical reviews are undertaken by either the Aboriginal Health Research Ethics Committee (AHREC) of South Australia or the WA Aboriginal Health Ethics Committee for Western Australia, in the Southern and Barkly regions of the Northern Territory.

An overview of national regulation and legislation for clinical trials is outlined below. An overview of jurisdictional legislation and policies is provided in Section 4 and referenced in the compendium provided at Attachment 2.

National regulation, legislation and policies

Regulation, legislation and guidance material for undertaking clinical trials exists at the national level and in some jurisdictions. Several participants interviewed expressed limited understanding of how jurisdictional policies and process aligned with national regulation, legislation and guidance material.

The Therapeutic Goods Administration (TGA) is responsible for enacting the regulation for therapeutic goods under the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 199 under two schemes:

- The Clinical Trials Notification (CTN) scheme
- The Clinical Trials Exemption (CTX) scheme.

The TGA provide guidance materials including the Australian Clinical Trial Handbook, September 2018, and the annotated Guidance for Good Clinical Practice 2016 (ICH-GCP).

National legislation and guidance material

National legislation is provided under the Human Research Ethics Committees and the Therapeutic Goods Legislation (under review, May 2017), and the National Statement on Ethical Conduct in Human Research (2007, updated in 2018) (the National Statement) provide guidelines developed in accordance with the *National Health and Medical Research Council Act 1992*. The National Statement requires that all clinical trials (whether they fall under the CTN or CTX schemes or not) be approved by a properly constituted HREC. The Australian Code for the Responsible Conduct of Research (2007 & 2018), guides institutions and researchers in responsible research practices and promotes research integrity and assists institutions in developing their own employee codes of conduct.

The Australian Code for the Responsible Conduct of Research (2007 & 2018) provides a framework for, managing research data and materials, publishing and disseminating research findings, including proper attribution of authorship, conducting effective peer review and managing conflicts of interest. It also explains the responsibilities and rights of researchers if they witness research misconduct and how to manage breaches of the Code and allegations of research misconduct. Developed jointly by the NHMRC, the Australian Research Council and Universities Australia, the Code has broad relevance across all research disciplines.

The NHMRC Research Governance Handbook: Guidance for the national approach to single ethical review (2011) guides the reader through the components of a research governance framework for multi-centre human research and describes the roles and responsibilities of key stakeholders within the framework. The handbook describes the research governance framework and its relationship with ethical review. Both ethical review and site assessment are components of research governance. The handbook also emphasises that research governance is the responsibility of the institution where the research is being conducted, and institutional considerations related to undertaking research in the context of the institution's policies, strategic priorities, expertise, resources, contractual arrangements, financial issues and approach to risk management.

The NHMRC Good Practice Process for Site Assessment and Authorisation Phases of Clinical Trial Research Governance (2016) (the Good Practice Process) v2.3, comprises three parts including the high-level principles and critical success factors that set out the ideal features of the research governance process. To examine the implementation of the process, a Clinical Trial Liaison Officer pilot program was undertaken which demonstrated the role significantly improved clinical trial time start-up times.

The Australian Government, Therapeutic Goods Administration - Fees and charges: summary (2018), the Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) schemes provide two avenues for conducting clinical trials involving the use of unapproved therapeutic goods. This document provides fees for clinical trials of unapproved medicines, unapproved biologicals, unapproved medical devices and unapproved other therapeutic goods.

The Online Forms website is an online system that enables users to complete their applications for research electronically. The website hosts a licensed copy of the NHMRC's Human Research Ethics Application (HREA), as well as the NSW Health and SA Health Site-Specific Assessment (SSA) Forms. Online Forms continues to operate for applications in ACT, NSW and SA.

The NHMRC Guidance on Data Safety Monitoring Boards (2018) (DSMBs) is a guidance document that clarifies the role and functioning of DSMBs. DSMBs are an independent and multidisciplinary group established by the trial sponsor to review, at intervals, accumulating trial data, in order to monitor the progress of a trial and to make recommendations on whether to continue, modify or stop the trial for safety or ethical reasons. A DSMB (or equivalent) monitors the risks associated with clinical trials including to participant safety, risk of data validity, real or perceived conflicts of interest and the risk to trial credibility.

Data retention, storage, disposal and archiving

The *Archives Act 1983* states that relevant documents in the custody of a Commonwealth institution may be required to be dealt with in accordance with the *Archives Act 1983*. The TGA requires records to be retained by the trial sponsor for at least 15 years following the completion of a clinical trial. However, in Australia, the overriding consideration for trial sponsors with respect to record retention is the issue of product liability and the potential need for product sponsors to produce records at any time during, and possibly beyond, the life of a product in the event a claim is made against the sponsor. Certain sections in the *Health Records (Privacy and Access) Act 1997 (ACT)* must be followed before giving access to a medical record to a person other than the patient.

Human Research Ethics Committee review and approval

Around half of the interview participants identified quality of HREC review as an important component of a national approach to HREC review and approval. Participants suggested that obtaining qualitative feedback regarding the robustness, efficiency and effectiveness of the processes, the experience of sites and the satisfaction of researchers would be extremely valuable to streamlining HREC review.

The former National Mutual Acceptance Jurisdictional Working Group was formed cooperatively by jurisdictions in 2013 to oversee implementation of the National Mutual Acceptance (NMA) scheme. In particular, for single ethics approvals to minimise variation for health services acceptance of an ethical review across jurisdictional borders for Phase II, III and IV clinical trials. When the NMA was implemented, jurisdictional indemnity and insurance arrangements in the public sector were not identified as a barrier to the national scheme. Interview participants consistently identified the NMA scheme as a key enabler for clinical trials in Australia and agreed that for trials approved under the NMA scheme, ethics approval time-frames are now largely on par with international competitors. However, interview participants also identified ongoing barriers to the implementation of the NMA in particular across the private and public sectors, and suggested this could be related to the following factors:

- The review and approval of clinical trial by a private HREC is not currently accepted by a public health service organisation
- Some jurisdictions have policies in place that prevent acceptance of HREC review and approval of a clinical trial by another jurisdiction
- Some HRECs in the private sector may not have the appropriate level of indemnity of the HREC and committee members to facilitate acceptance of private HREC review in the public sector.

To provide insights into this issue, an overview of indemnity and insurance requirements relating to HRECs are outlined below.

Insurance and indemnity

The ethical principles underpinning insurance and indemnity requirements relating to clinical trials are set out in the National Statement. Insurance and indemnity arrangements ensure that an institution or sponsor is able to compensate participants who are harmed in a trial. For this reason, evidence of appropriate insurance and indemnity arrangements are provided as part of the documentation submitted for ethics review. In 2014, the NHMRC engaged Rallis Legal to report on indemnity and insurance arrangements for clinical trials in the public and private sectors (the Report). The Report outlined the requirements for indemnity and insurance for state and territory HRECs. The Report considered issues regarding the indemnity and insurance arrangements for clinical trials that would prevent a public health service from accepting ethical review performed by an external or private sector HREC. The Report noted several jurisdictions have developed practices that may prevent a public health service under their jurisdiction from accepting ethical review performed by a HREC outside that jurisdiction, whether in the private or public sector. The expectation and practice of public health services is that all members of their HRECs are covered by the public health service's indemnity and insurance provisions, but this may not be the case for HRECs in the private sector.

In the public sector, each state and territory provides indemnity or insurance coverage in relation to their clinical trial activities. The arrangements take the form of insurance or

an indemnity fund or a self-insurance scheme. In the private sector clinical trials coverage is usually a subset of the medical indemnity or professional indemnity coverage. Interview participants suggested further clarity on the barriers impacting acceptance of the NMA across the public and private sector, is needed.

Guardianship and consent

NHMRC participant information and consent forms are designed for three categories of participants as identified by the National Statement: individual participant, child participant and participants unable to provide consent.

Guardianship and consent legislation were identified as causing confusion and presenting barriers to recruiting patients to clinical trials in some populations or clinical groups. One participant identified that, in NSW researchers must obtain approval from the HREC and then the NSW Civil and Administrative Tribunal (NCAT) for a clinical trial involving a person unable to consent as defined by the *Guardianship Act 1997 (NSW)*.

The NCAT has interpreted the definition of 'clinical trial' broadly and it was suggested that if researchers think they might be conducting a clinical trial where they intend to enrol participants who lack capacity to consent, they should approach NCAT formally for its approval. This requirement has particular relevance to emergency medicine and intensive care clinical trials, where there is often a time imperative impacting the process required to embark upon a legal process to determine the authority able to make decisions on behalf of a particular patient.

Legislative variation in consent by minors was also identified as being a barrier to conducting trials with children. These variations, and the lack of understanding around them, had the potential to cause non-compliance with the legislation. The NHMRC National Statement on Ethical Conduct in Human Research (2018) states:

> *It is not possible to attach fixed ages to each level – they vary from child to child. Moreover, a child or young person may at the one time be at different levels for different research projects, depending on the kind and complexity of the research. Being responsive to developmental levels is important not only for judging when children or young people are able to give their consent for research: even young children with very limited cognitive capacity should be engaged at their level in discussion about the research and its likely outcomes.*

Consent and impaired capacity to provide informed consent

The TGA requires freely given informed consent, is obtained from every subject prior to clinical trial participation. When a clinical trial (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g. minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent. This requirement is outlined in the Guidance for Good Clinical Practice (2016).

Consent of minors

The *Family Law Act (1975)* has provisions that can be applied in those Australian jurisdictions that have no specific legislation in relation to the issue of minors' consent to medical treatment. The National Statement outlines that researchers must respect the developing capacity of children and young people to be involved in decisions about participation in research. The child or young person's particular level of maturity has implications for whether his or her consent is necessary and/or sufficient to authorise participation.

Different levels of maturity and of the corresponding capacity to be involved in the decision include: (a) infants, who are unable to take part in discussion about the research and its effects; (b) young children, who are able to understand some relevant information and take part in limited discussion about the research, but whose consent is not required; (c) young people of developing maturity, who are able to understand the relevant information but whose relative immaturity means that they remain vulnerable. The consent of these young people is required, but is not sufficient to authorise research; and (d) young people who are mature enough to understand and consent, and are not vulnerable through immaturity in ways that warrant additional consent from a parent or guardian.

Victoria has amended its legislation so that children with decision-making capacity are able to consent (or otherwise) to medical treatment and research. Other jurisdictions have age

restrictions (e.g., in Tasmania, decision-makers must be 18 years old), other jurisdictions have a combination of age restriction or the ability to understand the nature and risk of the treatment.

Privacy

The *Privacy Act 1988 (the Privacy Act)* and guidelines approved under *Section 95A of the Privacy Act 1988 (revisions 2014)*, in conjunction with state and territory privacy laws, provide laws which relate to the protection of health information that is collected, used or disclosed in the conduct of research and the compilation or analysis of statistics, relevant to public health or public safety, and in the conduct of health service management activities. The Australian Office of the Information Commissioner established under the *Australian Information Commissioner Act 2010*, acts as the national data protection authority. There are a number of sections under the *Privacy Act 1998* that relate to the collection, storage and dissemination of information relating to clinical trials including:

- Privacy Amendment (Enhancing Privacy Protection) Act 2012
- Australian Privacy Principles (APPs)
- NHMRC Guidelines approved under sections 95 and 95A of the Privacy Act 1988
- Australian Institution of Health and Welfare Act 1987
- Use and disclosure of genetic information to a patient's genetic relatives under Section 95AA of the Privacy Act 1988
- Embryo Research Licensing Legislation
- Gene Technology Act 2000
- Office of the Gene Technology Regulator
- Consent and Guardianship Laws in Australia.

New South Wales (NSW), Victoria (VIC) and the Australian Capital Territory (ACT) have specific health privacy legislation that covers all health service providers (public and private sector) in those jurisdictions. This means that private sector health service providers operating in NSW, VIC and the ACT must comply with both Commonwealth and state or territory privacy legislation when handling health information.

Queensland (QLD), the Northern Territory (NT) and Tasmania (TAS) have privacy legislation that applies only to their public sector, including public sector health service providers. Western Australia (WA) and South Australia (SA) do not have specific privacy legislation although SA has administrative directions and codes that apply to the public sector, including public sector health service providers. SA also has health care legislation that contains some privacy related provisions.

In certain circumstances, the *Privacy Act (1988, revisions 2014)* permits the handling of health information and personal information for health and medical research purposes, where it is impracticable for researchers to obtain an individual's consent. This recognises the need to protect health information from unexpected uses beyond individual healthcare and, the important role of health and medical research in advancing public health. To this end, the Privacy Commissioner has approved two sets of legally binding guidelines, which are contained within the National Statement, and researchers must follow these guidelines when handling health information for research purposes without an individual's consent. The guidelines also assist HRECs in deciding whether to approve research applications. The guidelines are produced under *Sections 95 and 95A of the Privacy Act 1988*:

- Guidelines under *Section 95 of the Privacy Act 1988*, which set out procedures that HRECs and researchers must follow when personal information is disclosed from a Commonwealth agency for medical research purposes
- Guidelines under *Section 95A of the Privacy Act 1988*, which provide a framework for HRECs to assess proposals to handle health information held by organisations for health research (without individuals' consent). They ensure that the public interest in the research activities substantially outweighs the public interest in the protection of privacy.

A researcher must provide the reviewing HREC with the material required under the NHMRC guidelines, including any information necessary to enable the HREC to perform its obligations. The researcher must explain how health information held by the Australian Government will be used or disclosed during the research and that this conforms to the legislative requirements. The HREC must, in making a decision under the NHMRC guidelines, consider the following matters:

- Identify and consider the Australian National Privacy Principles that might be breached in the course of the proposed research, including whether it is necessary for the research to use identified or potentially identifiable data, and whether it is reasonable for the research to proceed without the consent of the individuals to whom the information relates

- Ensure that the committee has the competence to determine if the public interest in the proposed research outweighs, or does not outweigh, to a substantial degree, the public interest in the protection of privacy. If the public interest in the proposed research outweighs, to a substantial degree, the public interest in the protection of privacy, the research should not be carried out. In reaching this decision, the HREC must have regard to the factors set out in the National Statement. The HREC must also consider whether the proposal complies with the relevant National Privacy Principals in respect of the collection, use and disclosure of health information for relevant purposes. The HREC must monitor proposals approved under the National Statement
- Institutions and researchers must ensure health information is collected, used and disclosed in accordance with the Guidelines approved under *Sections 95 and 95A of the Privacy Act*. Researchers must seek approval from the Australian Institute of Health and Welfare (AIHW) Ethics Committee for access to data held by the Institute
- Must ensure that it does not disclose any such information to any person unless the AIHW Ethics Committee has specified in writing that such disclosure is permitted.

Many interview participants identified privacy legislation as being one area of variation between jurisdictions. For example, *The Health Records (Privacy and Access) Act 1997 (ACT)* regulates the handling of health information by both public and private sector health service providers in the ACT. The ACT Health Services Commissioner is one of three Commissioners within the ACT Human Rights Commission and handles health record privacy complaints. Health and mental health information may be disclosed to a medical practitioner by authority of an applicant under the *Privacy and Access Act (1997)* and for studies in the ACT, a specific module must be completed in addition to the Human Research Ethics Committee Application (HREA). These dual legislative requirements have the potential to cause confusion; and interview participants raised concerns regarding levels of compliance with privacy legislation.

Closer alignment between jurisdictions could resolve these issues, although the difficulty of such alignment was acknowledged. Accordingly, it was suggested that regular updates and clear communication around legislative responsibilities and changes were necessary. Projects conducted by the NHMRC in this regard were good examples, but required updating.

Box 2. Privacy

A public health network reported that, as part of a trial involving over 300 participants, it sought data of a personal nature from its own medical records department, with consent of the participants. Prior to transferring the data, the medical records department requested sight of all consent forms rather than requesting sight of ethics approval.

This case highlighted the lack of clarity and understanding around the roles within the network, and where liability would rest if there was a breach of privacy.

Clinical Trial Registration

Under the Code all clinical trials must be registered on a publically accessible, International Committee of Medical Journal Editors (ICMJE) approved database, prior to the first participant being recruited. ICMJE requires trial registration as a condition of the publication of research results generated by a clinical trial. ClinicalTrials.gov or the Australian and New Zealand Clinical Trial Registry (ANZCTR) are registries where organisations and individuals can access to information on clinical trials. These registries provide the World Health Organization (WHO) Trial Registration Data Set as required by ICMJE. The requirement to register clinical trials was broadly acknowledged and accepted by all jurisdictions and across the private sector.

National initiatives

The Australian Government Department of Health is providing $1.3B over ten years from 2017-18 to support the National Health and Medical Industry Growth Plan to improve health outcomes and develop Australia as a global destination for medical sector jobs, research and clinical trials. This includes a $206M program extension for the rare cancers and rare disease and unmet need clinical trial program, and the $42M for the International Clinical Trials Program.

The key overarching national initiative driving reform and efficiency in the conduct of clinical trials is the *Encouraging More Clinical Trials in Australia* budget measure. Under this initiative, the Australian Government is providing $7million to jurisdictions over four years to 30 June 2021 to assist state and territory governments achieve system redesign in accordance with the revitalised Council of Australian Governments Health Council clinical trials agenda [see **http://www.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials**]. Among other things, this agenda seeks to establish central points of contact to improve system navigation for sponsors and participants, streamline trial processes and time to trial start-up, and improve workforce capacity. During the mapping activity, each jurisdiction referred to project plans developed in-line with the aim of this budget measure, to redesign locally operating clinical trial processes and systems.

Jurisdictions and the Commonwealth are collaborating on key measures to further strengthening Australia's clinical trial sector and the Clinical Trials Project Reference Group (CTPRG) was identified as playing a critical role in the development of processes to streamline research governance and ethics, and several interview participants referred to the various legislation, policies and guidelines identified in the mapping exercise, and were unaware of how these were aligned with national policies.

The Independent Hospital Pricing Authority (IHPA) Determination of standard costs associated with conducting clinical trials in Australia (2015) was considered useful, but not broadly implemented. The document outlines costs including standard items associated with conducting clinical trials in Australia. It was intended as a starting point for financial planning and contract negotiation by trial sites and incorporated an underpinning principle that clinical costs are intended to be applied only to clinical trial services that provided over and above the normal standard of care to patients.

The Clinical Trials Liaison Officer (CTLO) and the NHMRC Good Practice Process was also recognised for its positive impact on the efficiency of HREC and SSA review. However, participants acknowledged that some jurisdictions have yet to apply this process consistently across all hospitals conducting clinical trials.

In 2015/16, the CTPRG (in their previous capacity as the Clinical Trials Jurisdictional Working Group) developed the Framework for National Aggregate Statistics (NAS). In particular, participants identified the NAS as representing a key starting point for jurisdictions to report agreed measures of clinical trial operational performance. The NAS includes eight measures:

1. Number of new trials and breakdown by trial phase, and by sponsor type
2. Overall study start-up timeline (regulatory timeline)
3. Ethics and governance approval timeline
4. Human Research Ethics Committee (HREC) approval timeline
5. SSA/site assessment timeline
6. Trial recruitment: actual and planned number of participants recruited
7. Site recruitment: actual and planned number of participants recruited
8. Total inbound (internal and external) investment annually.

Jurisdictional participants frequently referred to the Clinical Trial Networks and the AHRTCs as also supporting the streamlining of clinical trials processes (Box 3), although there was less awareness of the capacity of AHTECs to work with local trial sites to implement improvements.

Box 3. Case study – Advanced Health Research and Translation Centres (AHRTCs)

Through the Medical Research Future Fund (MRFF), the Australian Government has funded the NHMRC to establish Advanced Health Research and Translation Centres (AHRTCs) to

> *"identify and recognise leading centres of collaboration that excel in health and medical research, the translation of evidence into excellent patient care, and demonstrate a strong research and translation focus in the education of health professionals, at an international level" (NHMRC website).*

In March 2015, the NHMRC recognised the first four AHRTCs:

- Melbourne Academic Centre for Health
- Monash Partners Academic Health Science Centre
- South Australian Academic Health Science and Translation Centre
- Sydney Health Partners.

In 2017, a further four AHRTCs were recognised:

- Brisbane Diamantina Health Partners
- Sydney Partnership for Health, Education, Research and Enterprise
- Western Australian Health Translation Network
- NSW Regional Partners.

The Monash Partners Academic Health Science Centre provides professional development opportunities and programs including in Good Clinical Practice. It's Cross Partnership Research Ethics and Governance Working Group has worked to standardise governance forms across sites, established national patient registries, and played a lead role in establishing the Australian Health Research Alliance (AHRA), a national alliance of academic health science centres.

The South Australian Academic Health Science and Translation Centre is supported by an Executive Group and the Translational Health Committee which implements the model and strategic plan.

Sydney Health Partners is made up of the Sydney, Northern Sydney and Western Sydney Local Health Districts; the Sydney Children's Hospitals Network (Westmead); the University of Sydney; and nine affiliated independent medical research institutes.

Brisbane Diamantina has 10 partners and has focussed its Strategic Plan on key clinical themes including Ageing, Brain and Mental Health, Cancer, Skin and Skin Cancer, Chronic Disease, Evidence and Innovation in Clinical Care, Immunity, Inflammation and Infection, Maternal and Child Health, Trauma, Critical Care and Recovery.

The Sydney Partnership for Health, Education, Research and Enterprise (SPHERE) is formed of three universities, two Local Health Districts, seven Medical Research Institutes, nine major teaching hospitals, and ex officio, the NSW Ministry of Health. It has clinical academic groups across twelve streams.

The Western Australian Health Translation Network brings together Western Australia's major hospitals, medical research institutes and five universities. Its work incorporates key themes of health care that are informed by the WA Clinical Services Plan 2010-2020.

Private and not-for-profit sector initiatives

The volume of trials in Australia are predominantly delivered in public hospitals with the private hospital sector expanding this reach to deliver clinical trials more broadly, particularly in cancer care. Interview participants identified several key initiatives to streamline the delivery of clinical trials in the private and not-for-profit sectors.

In the private hospital sector, St Vincent's Hospital Melbourne (SVHM) is in the process of implementing a Research Valet program[3] as a single point of contact for trial sponsors and to improve the efficiency of the pre-approval process and activities related to trial site start-up (Box 4). Ramsay Health care has established the Ramsay Hospital Research Foundation, and the development of a research governance framework is due to be finalised in early 2019. Similarly, St John of God Health Care has employed a Clinical Trial Liaison Officer (CTLO) based on the NHMRC recommendations.

Bellberry Limited, the not-for-profit NHMRC certified HREC that provides eight HREC meetings per month and a complete HREC review within 20 days, is leading the Clinical Trials: Impact & Quality (CT:IQ) initiative. The CT:IQ initiative is an alliance of stakeholders involved in clinical trials with the aim to develop and implement strategies to improve the efficiency of clinical trials in Australia. This is based on the successful Clinical Trials Transformation Initiative (CTTI) in the United States of America which was established to generate evidence to guide best practice and consider the best way to undertake and generate clinical evidence. Of note, the CTTI is currently considering training standards for investigators.

Praxis is a not-for-profit organisation working through paid membership to engage across private and public sector organisations to deliver education and training and a number of interactive forums. An overview of the activities of the Australian Clinical Trials Alliance (ACTA) is provided in Box 5.

Box 4. Case study – St Vincent's Hospital Melbourne (SVHM) Research Valet® program

With the aim of making SVHM a premier and preferred site to conduct sponsored clinical trials across a broad range of clinical disciplines, SVHM has recently introduced the Research Valet® Service.

How it operates

The service links to the SVHM HREC which is credentialed for National Mutual Acceptance and provides services for all types of clinical trials, from first-in-man, Phase 1 through to Phase 4, and across pharmaceutical, diagnostics and med-tech trials.

The service includes full HREC submission preparation and liaison throughout the submission and approval process. St Vincent's Hospital Melbourne is not required to be a participating site to utilise this service.

Sponsors or researchers will receive final outcome notification within 30 days of HREC meeting and governance approvals will be targeted at seven days after submission of all required documentation.

Box 5. Case study – Australian Clinical Trials Alliance

The Australian Clinical Trials Alliance (ACTA) is a national peak body supporting and representing the networks of clinician researchers that conduct investigator-initiated or "public-good" clinical trials within the Australian health system.

Investigator-initiated or “public-good” clinical trials are of critical importance to patients who receive care within the health system, and to the functioning of the health system itself, because they address important gaps. Clinical Trials Networks are groups of practising clinician researchers (often several hundred per network) that come together to design large multi-centre clinical trials. Some also conduct trials in collaboration with industry but the majority focus on investigator- initiated trials. Networks extend across jurisdictional borders. These networks bring together hundreds of doctors, nurses, allied health and research professionals working in acute or primary care settings to design and conduct trials that provide definitive evidence about which treatments work, which don’t and which are most cost-effective in the real-world context of clinical practice.

The long-term collaborations that networks establish help to build world-class expertise in the design and conduct of trials, create research efficiencies and ensure that the benefits of clinical research are distributed widely across the health system. Clinical trials networks, led by senior clinicians working within the Australian health system, are particularly effective at conducting high-impact, public-good clinical trials. The majority of networks focus on investigator-initiated or public good trials, which are of critical importance to patients who receive care within the health system, and to the functioning of the health system itself, because they seek to address important gaps and health care questions that are unlikely to be addressed by other mechanisms. Some networks also conduct trials in collaboration with industry.

ACTA is supported by more than 50 clinical trials networks, trial coordinating centres and clinical quality registries. These groups cover a broad range of disease groups and clinical disciplines and represent a large proportion of the public-good clinical research conducted in Australia each year.

The first tranche of seed funding to support the establishment of ACTA was provided by the Victorian Department of Health in 2013, followed by official launch in March 2014. Much of ACTA's work is conducted with help from the sector's working clinician-researchers who generously give their time to participate in our Reference Groups and Special Interest Groups. A 2016 EY report Scoping and analysis of Issues in recruitment and retention in Australian clinical trials commissioned by the Australian Government on behalf of the then Clinical Trials Jurisdictional Working Group, recommended that the Australian Government Department of Health, the NHMRC, and Australian Clinical Trials Alliance, to formalise the structure, roles and support for clinical trials research networks be formalised, and that ensuring that they reflect national, consumer and community priorities for research.

Networks extend across jurisdictional borders.The networks recruit large numbers of patients or complete trials in smaller sub-groups of patients through broad national and international collaboration. The long-term collaborations that networks establish help to build world-class expertise in the design and conduct of trials, create research efficiencies and ensure that the benefits of clinical research are distributed widely across the health system.

A 2016 EY report Scoping and analysis of Issues in recruitment and retention in Australian clinical trials recommended that the Australian Government Department of Health, the NHMRC, and Australian Clinical Trials Alliance, to formalise the structure, roles and support for clinical trials research networks, ensuring that they reflect national, consumer and community priorities for research.

In June 2017, funding was provided to ACTA through the Medical Research Future Fund (MRFF) for four years as part of its broad aim of transforming health and medical research

and innovation to improve lives, building the economy and contribute to health system sustainability through targeted strategic investment across the research pipeline.

The Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program, under which ACTA is funded, supports Clinical Trials Networks (CTNs) to strengthen sector capability and collaboration with the aim of embedding evidence based care in the health system.

Under Funding Agreement with the Department of Health, ACTA is tasked to:

- Analyse the current CTNs landscape, including identification of key opportunities and priorities for enhancement and efficiencies to support a vibrant research sector
- Identify critical success factors for establishing and operating efficient high-impact CTNs
- Develop a national capacity building framework for CTNs
- Develop and implement best practice standards and guidance to bolster the capability of the sector
- Conduct multi-stakeholder forums for improving quality and efficiency of trials in Australia
- Facilitate cross-sector collaboration, including between CTNs and large trial coordinating centres, to support the investigator-led clinical research sector in adapting to novel methodologies and technologies tailored to support the needs of individual CTNs and CQRs
- Build and support the formation of new networks and capacity of existing networks and/or registries in areas of priority to key stakeholders, the Australian health system and the health and medical research sector in Australia
- To assist CTNs and CQRs to work productively and with central points of contact being established through jurisdictional redesign of trial operating systems
- Provide support to relevant Government initiatives and agendas
- Show progress towards a self-sustaining Clinical Trials Network to support the health and medical research sector into the future.

Section 3

Discussion elements

Interview participants commented on a number of initiatives planned or implemented as a direct response to identified variation in jurisdictional clinical trial operations. In particular, variation in timely ethics and governance review and approval processes, a transient workforce and a failure of sites to recruit the agreed number of trial participants and retain patients on a trial were considered contributing factors impacting Australia's attractiveness as a preferred location for clinical trials. Variation has resulted in frustration, confusion and accidental non-compliance by sponsors, investigators and trial site staff, and the evidence underpinning this view is that Australia is no longer on the pharmaceutical industry's preferred list of countries to conduct clinical trials. It also identified the lack of available information regarding high-performing sites and high performing researchers as contributing to fewer commercially sponsored clinical trials in Australia.

The common view expressed supported the publication of operational metrics using indicators such as the NAS to increase transparency and enable sponsors to select high performing sites and health services to identify issues and processes impacting their clinical trial operational performance. Safety reporting on Adverse Events (AEs) and Serious Adverse Events (SAEs) occurs throughout a trial, and an annual report is required to be submitted by the lead investigator for each trial undertaken. The annual report is submitted to the lead HREC and local site governance office and contains valuable information on the safety and quality of trial conduct, that is, the reporting of SAE and AEs and changes in trial site staff and the number of participants recruited, yet these reports are blind to sponsors and health service administrators. Contributing information contained in the annual report could edify NAS reporting, with measures on the safety and quality conduct of the trial.

Interview participants from the public sector typically agreed that research should be part of routine clinical care and closer organisational oversight would increase the efficiency and effectiveness of local site governance review and approval processes. Participants noted that in health services where there was variation in health service provision, the barriers to conducting clinical trials were also magnified. A minority of participants in the private sector disagreed with the attribution of fewer clinical trials to jurisdictional variation in questioning the evidence on which these assertions were based. These respondents identified that Australia has much to offer in site capability and investigator expertise and suggested that if a sponsor wants to have a specific clinician/site conduct the trial, they will approach them regardless of the duration of approval and costs. However, they agreed that undertaking a clinical trial in health services where there was broad organisational support for providing high quality clinical services and research, the ease of HREC application and the review process was clearly mirrored in the efficiency of their policies and processes.

Roles and responsibilities

References to the national and jurisdiction guidance material outlining the roles and responsibilities of sponsors, trial investigators and trial sites are provided at Appendix 3. Various views were expressed on the definition of 'governance', and the difference between HREC review and approval and research governance site-specific review and approval. The functions of the governance office and governance officers' roles and responsibilities in providing site-specific assessment of a clinical trial were considered similarly capricious.

For example, there were differing views as to whether research governance officers should undertake budget negotiations and contract review, or simply acknowledge the HREC approval, ensure the capacity of the site to undertake the trial, the receipt of appropriate documentation and facilitate execution of the contract. The absence of clearly defined roles and responsibilities for all parties involved in clinical trials was noted by the majority of interview participants.

Workforce

Participants suggested the lack of tenured positions for clinical trial staff and the endemic use of temporary contracts to employ clinical trial coordinators have impacted the ability of health services to retain a skilled and reliable workforce. This issue was also highlighted in a recent Scoping and Analysis of Clinical Trial Recruitment undertaken on behalf of all jurisdictions by the Department of Health. Similarly, approaches to workforce education and training are reportedly variable across the public and private sector. These two workforce factors were considered interlinked and presented a substantial barrier to efficient trial conduct. Additionally, high staff turnover, minimal organisational oversight, poor adherence to quality processes and limited or absent risk management has created a capability gap and a lack of understanding of key roles and responsibilities.

In order to recruit and retain the right people, it was considered critical to identify the skills required for undertaking roles such as trial coordination and local site governance review, or SSA. Likewise, participants suggested fewer safety incidents and protocol deviations would be realised as a result of appropriate induction, education and training and credentialing of clinical trial staff.

HREC review and approval

Participants recognised the benefits of the NMA in streamlining processes related to the ethical review and approval of a clinical trial. However, opportunities for expanding its applicability and therefore the efficiency of ethics processes remain. For example, participants supported the inclusion of all jurisdictions, including TAS and the NT. Participants also identified the need for more education on the applicability of the NMA across health services within NMA signatory, as there was some misunderstanding within and between jurisdictions regarding the implementation of the scheme. Additionally, participants suggested the need for the NMA to be expanded to private hospitals, not-for-profit hospitals and universities to make it a truly national scheme. Issues around external entity agreements for ethics approval were identified as only a handful of jurisdictions agreed to extend their ethics approvals to private or not-for-profit sites. Similarly, the public sector will not accept ethics approvals conducted by private and not-for-profit HRECs and the rationale for this is not stated in guiding documents. Participants also expressed frustration that different sites wanted to use different formats for annual reporting and there was little consistency within or between jurisdictions.

The exchange of external entity agreements was identified as being common in NSW[4] but not in other jurisdictions. These agreements mean that ethics approval from a public HREC for public sites can be extended to include private hospitals. However, it was noted that in jurisdictions without such agreements in place, sponsors may have to obtain three or more different ethics approvals in order to conduct trials in not-for-profit and private hospitals – which reportedly reduced the volume of trials being conducted in this sector. It was also noted that a consistent approach to the review of proposals for research involving Aboriginal and Torres Strait Islander people was required rather than the ad hoc approach currently in place.

Information management systems

Disparate information management systems for ethics and governance processes were frequently identified as impacting variation. The role of technology was recognised as being important for the efficiency of ethics and governance document submission and approval. For example, it was noted that some sites do not accept electronic submissions and others do not accept electronic signatures. Until recently, several jurisdictions used Online Forms for ethics and, to a lesser extent, the online SSA application module. While TAS and NT have their own discrete processes, there are now four information systems for ethics applications nationally:

- Online Forms (ACT and SA. Note: NSW still using Online Forms for SSAs and HREAs for NMA studies)
- Ethics Review Manager (ERM) Forms (VIC, QLD and Mater Health)
- Research Ethics and Governance Information System (REGIS) (NSW and ACT in transition)
- Research Governance Service (RGS) (WA).

This variation reduces the efficacy of the NMA as there is confusion around how or when proposals must be submitted to different jurisdictions on two (or more) separate systems for ethics approval. Only NSW Health and SA

Health have SSA forms on Online Forms, and several jurisdictions have discrete modules within the approval forms. While participants noted the importance of privacy and protecting intellectual property, it was suggested that a centralised information management system would enable sponsors and trial site staff to see the progress of applications, and increase transparency in the process. Participants broadly supported the proposed national 'front-door' initiative as a single information management system that would facilitate harmonisation of trial document submission and management processes.

Budgets and costs

Budget negotiations and costing were frequently identified as a source of delay in the pre-approval process. Several participants recognised discretionary costs were applied against the list of standard items associated with conducting a clinical trial in Australia. The standard cost structure developed by IHPA has not been broadly applied and several participants did not understand how the cost structure had been developed. In addition, there was significant variation in fees for ethics and governance approvals across both the public and the private sector.

Participants typically agreed that streamlined methods for budget negotiations and greater transparency with regard to costs and fees would increase the appeal for conducting clinical trials in Australia. Methods for streamlining budget negotiations could be relatively straightforward as evidenced by the availability of costing tools developed by WA Health and NSW Health. Participants were amenable to a strategy to develop standard costs for clinical trials that would ideally deliver a classification system to cost types of trials and calculate cost drivers.

Contracts and Agreements

Participants noted standard contracts and Clinical Trial Research Agreements (CTRA) improved the efficiency of negotiating the conduct of clinical trials. Health Departments in NSW, QLD, VIC, SA and TAS, together with South Eastern Border States (SEBS) Committee and Medicines Australia revised and updated five Clinical Trial Research Agreements (CTRAs):

- Clinical Trial Research Agreement – Medicines Australia Standard Form
- Clinical Trial Research Agreement – CTRA: Contract Research Organisation acting as the Local Sponsor
- Clinical Trial Research Agreement – Collaborative or Cooperative Research Group (CRG) Studies
- Clinical Trial Research Agreement – Phase 4 Clinical Trial (Medicines)
- Clinical Trial Research Agreement – Phase 4 Clinical Trial (Medicines) Contract Research Organisation acting as the Local Sponsor.

Links to these five agreements are housed on the Medicines Australia website. Each externally-sponsored clinical trial conducted in a public health organisation, whether by a commercial entity or a not-for-profit organisation (such as a collaborative research group), must be governed by a Clinical Trial Research Agreement. The agreement is reviewed by the public health organisation during the site-specific assessment process. It was noted that WA has developed its own standard jurisdiction-wide form. Interview participants typically agreed that harmonised forms would be beneficial if they were applied nationally and across the private and not-for-profit environment and university sectors.

Box 6. Agreements

Clause 3.2 of the Clinical Trial Research Agreement (CTRA) – Medicines Australia Standard Form identifies that the Institution agrees to be responsible for the acts and omissions of the Principal Investigator in relation to the conduct of the Study, to the extent that such responsibility would attach to the Institution in accordance with its obligations under this Agreement or under the common law on the basis that the Principal Investigator is acting as an employee of the Institution.

Within the private health sector, many institutions have different engagement relationships with investigators. Accordingly, it was submitted that any private hospital that's signing a CTRA in the Medicines Australia format is accepting liability if the principal investigator doesn't fulfil requirements within the agreement.

Section 4

Expectations of the National Clinical Trials Governance Framework

There were no objections to the development of a National Clinical Trials Governance Framework (Governance Framework) and there was significant interest in its development and feedback on its content and applicability. Broadly, the anticipated benefits were for the potential to improve:

- The quality of the preapproval processes
- Consistency in trial processes
- Compliance with policies and process
- Transparency for sponsors, investigators and institution staff
- Trust and collaboration across the sector
- Culture of research in the hospital sector.

> A framework [needs to be] robust and able to be implemented, but flexible and take into account the diversity of trial sites.
>
> *Interview participant*

Application of the Governance Framework

There was limited awareness of how 'governance' was defined in the context of the Governance Framework. None-the-less, participants thought the framework needed to be relevant to all research settings including public, private and not-for-profit hospitals, universities and community health settings, for both commercially sponsored and investigator-led studies.

Interview participants provided suggestions on the potential content of a framework and considered components of the Governance Framework that would have the greatest impact on the sector. Both ethics and workforce were considered to fall within the purview of a Governance Framework. Participants commented on the importance of open communication between key individuals delivering a clinical trial and agreed that standards alone cannot be effective without a robust accreditation process.

It was felt that accreditation would ensure uptake and compliance with the Governance Framework and that performance and accreditation results should be made publicly available. Transparency was frequently identified as being critical in driving improvement.

Similarly, accountability and review mechanisms were preferred components of the framework including a complaints system, and independent management of complaints to ensure compliance and avenues to investigate potential breaches. Participants wanted to ensure consumers were recognised in the Governance Framework and that their voice and interests were reflected, particularly around consent and risk management.

The majority of participants identified site accreditation as a method for measuring the success of the Governance Framework. In order to obtain accreditation, it was generally agreed that metrics or key performance indicators (KPIs) should be required as part of the Governance Framework and therefore accreditation, and that audits should be carried out to ensure accurate reporting against those metrics (rather than self-reported metrics alone).

Timeliness was the key factor in measuring success of the framework. KPIs identified during the interview process frequently aligned with those in the NAS, and several participants suggested the following metrics could be considered for inclusion:

- Time to ethics approval
- Time to governance approval
- Study start-up
- Time to first patient recruited
- Time spent preparing ethics / governance, regulatory and contractual documents
- Time spent reviewing ethics / governance, regulatory and contractual documents
- Time to approval (including amendments).

Participants identified metrics other than time measures including:

- Number of clinical trials (by site and by type)
- Number of participants recruited
- Number of trials that opened and closed without recruiting a participant
- Number of ethics approvals
- Number of governance approvals
- Growth in number of clinical trials (by site and by type)
- Level of investment (trial site and sponsor)
- Workforce related measures such as:
  - number of staff engaged in conduct of clinical trials – particularly as research governance officers and trial coordinators
  - proportion of trial coordinators engaged as permanent employees or on contracts
  - number of staff dedicated to coordinating clinical trials
  - skills of workforce / qualifications / accreditation
- Institutional accreditation
- Number of complaints
- Number of protocol breaches
- Timeline to resolving breaches.

Implementation was a key concern of many participants regarding the Governance Framework. It was suggested that a significant change management process would be required to avoid confusion during implementation. There was an expectation that the Governance Framework would provide clear guidance on which guidelines or policies apply and which are no longer relevant, as several participants found the web of legislation and policies difficult to navigate. Authoritative communication on the clinical trial regulatory framework was sought from jurisdictions, industry and the private and not-for-profit sectors. Consultation with consumers and the industry was considered critical prior to implementation.

Section 5

Jurisdictional legislation, policies and initiatives

Tasmania

The University of Tasmania applies the Responsible Conduct of Research Policy 2015 and formally acknowledges and adopts the principles and practices in Part A and B of the Australian Code for the Responsible Conduct of Research 2018.

The Tasmania Department of Health, including the Tasmania Health Services and Ambulance Tasmania, has contracted the University of Tasmania (UTAS) to provide the state-wide Human Research Ethics Committee (HREC) services for all research conducted with patients, clients or staff within the public health sector. The UTAS HREC committees operate in accordance with the NHMRC requirements.

The *Personal Information and Protection Act 2004 (TAS)* covers the Tasmanian public sector including public hospitals. The Office of the Ombudsman and Health Complaints Commissioner of Tasmania can receive and investigate complaints in relation to complaints under the Act. In Tasmania, there is also the Guardianship and Administration Act 1995 (TAS) and the *Guardianship and Administration Regulations 2007 (TAS)* which applies to the consent of minors and consent on behalf of a person unable to provide consent. A Person Responsible can give consent for a child under 18 years. Note: If a Person Responsible has given substitute consent in accordance with his or her responsibilities, that consent can override the patient's refusal to the proposed treatment.

Policies relating to consent and impaired capacity to consent are similar to those in South Australia and there is no legislation that specifically refers to consent given by a person with impaired capacity to participate in a clinical trial. There is no specific requirement for any tribunal or court to give approval to a research project or to otherwise give the requisite consent for a person who lacks the capacity to provide consent to participate in the research project. Consent to carry out medical treatment on a person who has impaired capacity to provide consent may be given by the Guardianship and Administration Board of Tasmania or by a Person Responsible for that person. Additionally, there are certain medical treatments that a Person Responsible cannot consent to, such as removal of tissue for transplant and those likely to lead to infertility. The Guardianship and Administration Board of Tasmania has a fact sheet regarding these procedures.

Research data is required to be managed in accordance with the University of Tasmania's Management of Research Data Policy and the Australian Code for the Responsible Conduct of Research. Each clinical trial is required to have a staff member dedicated to managing the research data.

For the conduct of clinical trials, the Medicines Australia Clinical CTRAs should be used, and for commercially sponsored trials of medical devices, the Medical Technology Association of Australia (MTAA) standard CTRA is recommended. The terms contained in these agreements cannot not be altered or amended in any way. As elsewhere in Australia, schedule clauses may be used for unique requirements. UTAS legal review is required for special clauses. All clinical trials must have appropriate indemnity. For commercially sponsored clinical trials the Medicines Australia Standard Form of Indemnity or the Medical Technology Association of Australia Form of Indemnity for medical device trials is recommended.

In Tasmania, all clinical trials must also have appropriate insurance cover. For commercially sponsored clinical trials, insurance cover must be provided by the sponsor and included in Schedule 4 of the Clinical Trial Research Agreements. For UTAS sponsored clinical trials, the principal investigator is responsible for ensuring the trial meets the University's insurance policy.

The Tasmania Department of Health is not a signatory to the NMA but considers applications that have received prior approval. There are four different applications in Tasmania which may be created using the HREA and submitted direct to UTAS. If the project already has approval from a NHMRC registered HREC, including clinical trials already approved for another Tasmanian site, a Prior Approval Application Form is required to be completed. Clinical trials which are determined to carry greater than 'low risk' and have not been approved by another NHMRC accredited HREC require completion of a full application. If a trial is to be conducted at a Tasmanian Health Service site, or a Department of Health and Human Services site/clinic it will need to receive governance authorisation from each site. A standard governance application form is available. The Clinical Trials Governance Coordinator checks this at the time of local site application. There are also low risk application forms. Fees for HREC review for a clinical trial approximate $6,600 and low risk HREC review is $3,025. There are additional fees for local site-specific assessment.

Australian Capital Territory

In ACT Health, the Research Ethics and Governance Office is responsible for the coordination and management of concurrent ethical and site governance review processes. This includes scientific and ethical review of new research proposals, site governance review and ongoing monitoring of the trial conduct. The Clinical Trials Sub-Committee provides advice to the ACT Health Human Research Ethics Committee (HREC).

The ACT is a signatory to the NMA, and additionally for trials in the ACT, the ACT Specific Module must be completed in addition to the Human Research Ethics Application (HREA). In 2016, ACT Health established the ACT Health Clinical Trials Committee (CTC) Terms of Reference. The CTC provides advice and recommendations regarding clinical trials and registry governance including assessment of clinical trials and monitoring of clinical trial and registry performance and outcomes. The ACT Health Clinical Trials Committee (CTC) is responsible for the review and authorisation of clinical trials, registry projects and biobanks conducted at or by ACT Health.

The CTC operates a two-step process:

1. Before any project commences the researcher and research unit must complete a feasibility assessment and submit to the CTC for an initial assessment. Once feasibility has been confirmed the CTC will issue formal correspondence advising of the next steps in the process
2. Following completion of budget negotiations researchers must submit a final budget, finance summary and research agreement to the CTC for authorisation.

The following Acts apply to consent and impaired capacity to consent in the ACT:

- *Guardianship and Management of Property Act 1991*
- *Medical Treatment (Health Directions) Act 2006*
- *Mental Health (Treatment and Care) Act 1994*
- *Powers of Attorney Act 2006*
- *Powers of Attorney Amendment Act (PAAA) 2016.*

Adults taking part in a research must give informed consent. Consent for participation in research may be given by a person holding an enduring power of attorney (medical and low-risk research), a guardian (medical and low-risk research) and a health attorney (low-risk research only). The *Powers of Attorney Amendment Act (PAAA) 2016* has provisions for two broad categories of medical research: low-risk research and medical research. Low-risk research is essentially research that poses no foreseeable risk of harm to the person. Medical research is research in relation to the diagnosis, maintenance or treatment of an existing medical condition or to which a person is at significant risk of being exposed and includes experimental medical treatment.

There are a number of safeguards and strict processes incorporated within the legislation to ensure decisions made by an attorney about an individual's participation in medical research to ensure particular standards are adhered to and to avoid potential abuse by attorneys. If an attorney requires any assistance in complying with the above process, they are able to apply to the ACT Civil & Administrative Tribunal to seek guidance.

If there is any doubt about an attorney's decision to authorise an individual's participation in low-risk research or medical research, the law allows an 'interested person' (e.g. a relative) to apply to the ACT Civil & Administrative Tribunal for a review of the attorney's decision.

The Children and Young People Act 2008 (ACT) directs a researcher to address in HREA whether any of the participants lack the capacity to give consent and how this will be managed. Legally a person can only consent to medical treatment (including examination) if they are an adult (aged 18 years) or if they are mature enough to clearly understand the nature of treatment and any risks involved. Otherwise, a parent or guardian should be asked to consent to treatment on behalf of the child or young person.

The Australian Code for the Responsible Conduct of Research applies in the ACT as well as the:

- *Information Privacy Act 2014 (ACT)*
- *Territory Records Act 2002 (ACT)*
- *Health Records (Privacy and Access) Act 1997 (ACT).*

An agency in the ACT must have an approved records management program and provide access to facilities for the safe and secure storage and management of research data, records and primary materials and, where possible and appropriate, allow access and reference both the *Territory Records Act 2002 (ACT)* and the *Health Records (Privacy and Access) Act 1997(ACT)*.

The following is necessary to meet the ACTs requirements for non-low risk ethics applications:

- The insurance certificate must specifically name the Australian corporate entity acting as commercial sponsor as a named insured under the relevant insurance policy
- The insurance certificate must include a valid coverage period for the policy
- If the certificate is provided in the name of an overseas parent company, it must name the Australian entity as a subsidiary
- The insurer providing the cover must be approved by the Australian Prudential Regulation Authority and must have a minimum financial strength rating of 'A' or above.

The ACT schedule of fees includes:

- CTN with commercial sponsor: $6,000
- CTX with commercial sponsor: $6,000
- Trials not instigated by commercial sponsor: $1,100
- Amendments to existing projects: $250 - $1,000
- Low risk projects: $60 - $80.

The fees for SSA are as above. That is, one set of payments is for ethics review fee and one for research governance review.

ACT Health initiatives

Since 2016, ACT Health undertook several initiatives to improve the local operating environment for clinical trials including a clinical trials governance framework, and the development of standardised templates and processes to be used in the approval process.

It has also conducted a scoping project which, similar to other jurisdictions and the private health sector has found support for standardisation in research processes across ACT.

Workforce challenges were identified as a key barrier to the efficient conduct of clinical trials as the majority of clinical trial staff were engaged on temporary (short-term) contracts or via secondment. The lack of career development in clinical research and the need for access to education and training for clinical trials staff were also recognised as barriers to retaining a skilled and reliable work force.

In late 2017, several meetings were held between research governance office staff at ACT Health, the ACT Director General of Health and local level government representatives regarding the absence of institutional oversight for research conducted in hospitals. A direct outcome of these discussions was the formation of a new committee to develop new institutional wide governance processes and a two-step process of clinical trial and health research review was implemented. The CTC, as discussed above, developed a template to be completed by the local site trial principal investigator and reviewed by the committee, to determine the suitability of the trial to be conducted within a hospital. That is, consideration of study feasibility and financial viability was undertaken for all clinical trials, registries and biobanks.

To design and implement this new approach to institutional governance, a scoping project was undertaken over four months. Every department undertaking clinical trials in ACT hospitals were surveyed to determine the volume and type of research being conducted and the needs of the researchers. The committee questioned whether it was preferred to develop a governance framework for biobanks specifically, and whether or not it was preferred to have biobanks as an independent organisational approach or contribute to a central biobank. More than 40 clinical registries had received approval by the HREC and the committee considered developing dedicated resources for registries.

The scoping exercise revealed enormous appetite for standardisation in research processes across ACT health services. Additionally, researchers and study coordinators requested the following to support their work:

- Standard operating procedures
- Time to undertake research
- Financial and business planning support
- Strategic planning for clinical trials
- Administrative support
- Support for staff training
- Avenues for career development and no scope for advancement.

A key measure of success identified by the committee would be to achieve local site governance review within 8 days. Additionally, there would be jurisdictional reporting to the hospital, Director General and Deputy Director General of Health, on annual reporting of operational metric provided in the ACT Health Annual Report, the establishment of network and research coordinators monthly meetings and the development of a reliable and skilled clinical trial workforce. To date, the following has been implemented:

- The establishment of the CTC
- Increased institutional awareness of the range of research
- Preference to avoid employing staff temp contracts and a general pool of staff (10-12 clinical trial nurses) to be seconded to clinical trial units
- Regular meetings with trial coordinators to discuss issues and develop strategies to resolve issues as they arise.

New South Wales

In NSW the Office for Health and Medical Research (OHMR) is the peak NSW body that oversees clinical trials. The policy directive issued by NSW Health OHMR is the *Research Authorisation to Commence Human Research in NSW Public Health Organisations (2010)*. This policy directive sets out the requirements for site authorisation by the local health district chief executive or delegates to ensure that human research meets appropriate governance standards through an effective and efficient system of review. Research governance officers are required to provide advice to investigators seeking to undertake human research within NSW public health organisations and to review applications for site authorisation and provide a recommendation to the chief executive or their delegate.

NSW Health, *Research Governance in NSW Public Health Organisations Guideline (2011)*, summarises the principles, standards and requirements and also the responsibilities and accountabilities of key parties involved in research taking place in NSW public health organisations. Public health organisations are responsible for using this guideline to develop their local operating procedures which clearly define the roles, responsibilities and accountabilities of parties involved in research taking place within their premises. Each university has its own governance framework. Standard operating procedures outline the role of research governance officers (employed by NSW Health). A comprehensive list of research and ethics policies to be applied in NSW are provided within Appendix 2 and outlined below:

- Ethical Review for External Entities
- Operations Manual: Human Research Ethics Committee Executive Officers
- Standard Operating Procedures: Human Research Ethics Committees
- Quality Improvement & Ethical Review: A Practice Guide for NSW
- Requirements of the *Human Tissue Act 1983* in relation to research and use of tissue Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations
- Standardised Patient Information Sheets (PIS)
- New South Wales Ministry of Health (2017) Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations.

The submission of research applications for ethics and site governance approval is via the AU RED (Australian Research Ethics Database). AU RED User Access Operational Procedure (2016) outlines the procedure of providing AU RED access to new users to undertake their duties as employees of NSW public health organisations and the removal of access for exiting AU RED users. The Operations Manual: Research Governance Officers (2010) instructs RGOs in the use AU RED for the management of applications for SSA. There is also the AU RED Data Collection and Reporting Instructions Manual. This document supplements the document Metrics for Health and Medical Research (2016), and provides AU RED data calculation parameters that OHMR will use to filter and analyse each metric.

AU RED is active, although it has been superseded by a new workflow management system REGIS. REGIS is a joint initiative between NSW eHealth and OHMR. This investment aligns with the investment into the REGIS work-flow tool by the ACT Department of Health and is anticipated to align with the TGAs on-line submission of forms relating to the CTN and CTX schemes. REGIS supports the workflow of documents required to be submitted for ethics and governance review of human research projects in all NSW and ACT public health organisations.

NSW is a signatory to the NMA and almost all research offices across NSW Health are now accepting single-centre applications in REGIS however, applications via the NMA are not included. Interview participants commented on the confusion caused by the implementation of REGIS and a minority were not supportive of this level of investment, as they felt that this was a move away from nationally harmonised forms processing.

In REGIS, the applicant completing project registration is asked to assign an overall risk category for all clinical trials. This web page provides additional guidance for the completion of that question, and for the use of the information for the HREC and institution. International risk assessment guidance from the Office of Economic Cooperation and Development (OECD) recommends an overall risk category is assigned to clinical trials.

This categorisation is based on the:

- Potential risks of the use of the investigational product/device in the trial relative to standard of care for the clinical condition
- Level of clinical experience with the intervention.

An SSA must be completed for all human research projects to be conducted at sites under the control of NSW public health organisations, even ones involving low or negligible risk to participants. An SSA is required if the project involves one or more of the following activities at a site under the control of a NSW public health organisation: enrolling participants into research (e.g. obtaining informed consent, screening) carrying out protocol-specific research procedures with or on participants and managing and analysing data, tissue and responses from surveys and questionnaires collected for or from research.

In relation to clinical trials, the *State Records Act 1998 (NSW)* also applies under section 21(2) of the Act. No part of the NSW public health organisation will be in breach of the Act if it complies with the General Retention and Disposal Authority: Public Health Services: Patient/Client records including:

- Patient/Client Records Administrative Records
- Disposal classes (Research Management) deal with records created for the management of the conduct of clinical and nonclinical research, trials or studies, etc. Disposal actions (including timeframes for retention) are listed against each disposal class
- Disposal classes (Research Management) that deal with records created for the management of the conduct and operations of projects, programs, trials or studies conducted for the purposes of advancing medical knowledge
- Disposal classes that deal with records relating to the establishment and meetings of ethics/research committees
- Disposal actions (including timeframes for retention) are listed against each disposal class
- Health Privacy Principles also require data storage to be secure, and not kept longer than necessary.

NSW uses the Medicines Australia CTRAs and where a commercially sponsored clinical trial is proposed to be conducted at a public health organisation the commercial sponsor must provide an executed indemnity in the form of the most recent version of the Medicines Australia Form of Indemnity for Clinical Trials and, evidence of insurance arrangements and an executed clinical trial agreement in the form of a standard CTRA, or other clinical trial agreement approved by the public health organisation. A commercial sponsor must also submit a certificate of currency of insurance that evidences current professional indemnity and products liability policy(s) (or equivalent) and must include clinical trials cover.

In NSW the following fee schedule applies:

- Commercial sponsor application fee: $3,300
- Non-commercial sponsor application fee: $150
- Amendments to existing projects: $550
- Fees for SSA for a commercially sponsored application is $3,740.

NSW Health initiatives

In response to the 2016 budget measure, Encouraging More Clinical Trials to Australia, two AHRTCs were established in NSW; Sydney Health Partners and The Sydney Partnership for Health, Education, Research and Enterprise (SPHERE). In 2017, and in partnership with the Office of Health and Medical Research, NSW Regional Partners was established to build collaboration between regional centres and NSW Health. The OHMR also leads and coordinates a number of collaborations between medical research institutes and local health districts. An example of one such collaboration with Sydney Local Health District is provided in Box 7.

Additionally, NSW Health OHMR provides the Operations Manual: Research Governance Officers (2010, revised 2018). These guidelines contain standard operating procedures for research governance officers employed within NSW public health organisations. These procedures outline the function of the research governance officer which includes pre- and post-authorisation responsibilities, as well as other ongoing responsibilities.

NSW Health, OHMR have also developed the framework for early phase clinical trials to build early phase trial capability and are working towards a quality recognition scheme of investigators and sites with capability to conduct early phase clinical trials. Work is underway through an expression of interest process to appoint specialist early phase clinical trial HRECs to review early phase clinical trials in NSW public health organisations. Notably, the expression of interest process is open to privately-run and not-for-profit HRECs. As research governance officers in public health organisations are the key enablers of research, NSW Health has developed a competency framework for research governance officers to ensure the NHMRC National Statement is interpreted uniformly across the state. Standard operating procedures for HRECs have also been developed and published.

The NSW Health, Operations Manual: Human Research Ethics Committee Executive Officers (2010) outlines the HREC role in monitoring approved research projects. The HREC role includes ensuring compliance with the conditions of approval and protecting rights, safety and welfare of participants. This role also includes review of annual progress reports and final reports, safety reports and reports of protocol violations. The HREC has the discretion to adopt other mechanisms for monitoring depending on the complexity, design and risk perceived.

The OHMR metrics on clinical trials are outlined in the 2017-2018 Service Agreement Data Supplement: Key Performance Indicators (and Associated Improvement Measures). The measures are the number of participants enrolled to commercial clinical trial projects as a proportion of those initially agreed to be enrolled per the Clinical Trial Research Agreement minimum target (as a percentage); and first participant enrolled by the site within 40 calendar days of site authorisation (as a percentage) and the number of persons recruited to cancer clinical trials. There are also metrics on ethics approval, research governance and SSA timeframes.

Cancer Institute NSW provides a reporting platform through which clinical trial operational measures are captured and reported to NSW Local Health District Chief Executives and Directors of Cancer Services. As of 1 July 2016, OHMR has collected data from NSW local health districts and specialty networks and NSW Ambulance to generate ethics and governance metrics for health and medical research, including clinical trials. As a result, several initiatives have been undertaken to improve the clinical trial operating environment more broadly. Ethics and governance approval metrics are now included in local health district service agreements. The service agreements set out the performance expectations for each local health district by the NSW Department of Health within the funding schedule. For the 2018-19 financial year the following metrics are included:

- HREC approval within 45 calendar days for at least 95% of non-low risk ethics applications
- Local hospital research governance office approval within 15 calendar days for at least 95% of site-specific assessment applications.

More recently, under the Council of Australian Governments Health Council budget measure, NSW Health have developed a framework for clinical trial support units that provides four functions: study start-up specialists; a designated clinical trial manager; a pool of coordinators and a quality manager to oversee the post-approval activities. A costing tool template for trial sites has been developed based on the costing template in the United Kingdom.[5] There is no dollar value in the template, so sites are able to enter their trial related income and expenditure against trial related activities. The IHPA cost structure has not been applied in NSW, although this cost structure would be considered if regular updates to the schedule were carried out. NSW OHMR is also undertaking a project to develop a standard confidentiality agreement to streamline the investigator review time of a clinical trial protocol with MTP Connect and Medicines Australia.

Box 7. Case study – Sydney LHD Research Strategic Plan 2018 – 2023

The Sydney LHD Research Strategic Plan was released in August 2018. The District Planning Unit supported the development of the plan which was led by the District Director of Research with oversight of the Chief Executive, through the Subcommittee of the Education and Research Board Committee. An extensive consultation process informed development of the plan.

Strategic directions

Three Strategic Directions were identified to achieve the vision of the LHD being a world leader in research:

- To invest in and sustain research capacity across all District facilities, professions and disciplines
- To create knowledge by leading quality biomedical, clinical, health services and population health research
- To implement knowledge by rapidly translating research into best practice and policy.

Priorities and activities

Priorities include:

- Ensuring consumer participation and community involvement in research
- Developing state of the art shared infrastructure
- Delivering District-wide research leadership and support services
- Developing and increasing access to quality research education
- Sustaining and growing world-class collaborations
- Strengthening high quality research, with a focused interdisciplinary and collaborative approach
- Harnessing the potential of clinical and population health data to inform research
- Enhancing translational research
- Expanding clinical trials capacity and participation.
- Supporting a quality approach to research ethics and governance
- Integrating the practice of implementation science across the District
- Evaluating to ensure effective implementation of research evidence.

Support a quality approach to research ethics and governance

In order to achieve this, the LHD will support implementation of REGIS, deliver user-friendly education for researchers about both ethics and governance processes, improve ethics and governance data collection and analysis and develop pathways for approval and oversight for Aboriginal research.

How success will be measured

A number of quantitative and qualitative measures are included in the report to identify whether the LHD has achieved its vision:

These include an increase in:

- Number of research grants, publications and citations
- Number of research students and staff
- Number and breadth of clinical trials and research studies
- Number and breadth of departments involved in research
- Number and breadth of research collaborations
- Number and breadth of commercialised research (products, licences and revenue).

Additionally, improvements are expected in:

- Patient experience
- Patient outcomes
- Health system efficiencies
- Health system research culture
- Economic and social benefits.

Northern Territory

In the Northern Territory the research office functions are provided through two offices; the Menzies School of Health Research with the Top End HREC, and the Central Australian HREC which operates under the auspices of the Centre for Remote Health, and considers applications for all human research being conducted for research undertaken in the adjoining tristate areas (AP Lands of South Australia or the Ngaanyatjarra lands of Western Australia).

The *Information Act 2003 (NT)* and Information Privacy Principles apply to NT public sector bodies, including to their handling of health information for the purpose of conducting medical research. The Information Privacy Principles set out 10 rules for collecting and handling personal information that bind NT government organisations. The Office of the Information Commissioner for the Northern Territory is the independent statutory body responsible for overseeing the privacy provisions of the Act and accepts complaints from consumers relating to the privacy of health information. The Health and Community Services Complaints Commission is also able to accept and resolve complaints about health, disability and aged services in the Northern Territory.

The Northern Territory does not have health specific privacy legislation, although the Code of Health and Community Rights and Responsibilities made under section 104(3) of the *Health and Community Services Complaints Act 1998 (NT)* confers a number of rights and responsibilities on all users and providers of health and community services in the Northern Territory. The rights and responsibilities set out in the Code of Health and Community Rights and Responsibilities do not override duties set out in Northern Territory or national legislation. Legislation for consent and impaired capacity to consent are provided by regulations:

- *Guardianship of Adults Act (NT)*
- *Guardianship of Adults Regulations (NT)*
- *Advance Personal Planning Act (NT)*
- *Advance Personal Planning Regulations (NT).*

This legislation applies to the making of decisions on behalf of an adult with impaired capacity to provide informed consent; an adult is a person who is at least 18 years of age and an adult with impaired capacity to provide informed consent including consent to participate in a research activity on the basis of:

- A consent decision specified in an advance personal plan (made by the adult while they did not have impaired capacity)
- Consent provided by a guardian appointed under a guardianship order
- Consent provided by a decision maker appointed under an advance personal plan or consent provided by the Northern Territory Civil and Administrative Tribunal.

Common Law in relation to consent for minors, and capacity to consent, applies for those under 18 years.

Medicines Australia HREC Review Only Form and certificate of insurance is required to be submitted for clinical trials in the NT. The National Statement is applied to undertaking risk assessment process and HREC applications may be developed using the HREA for multi-site projects, although review by an NT HREC is preferred depending on what the research entails regarding location, participants, and type of data. Additionally, the researcher may be required to obtain support letters and permits from other organisations and communities to accompany an ethics application, for example, a letter of support from the Director Medical Services or Director of Primary Health Care.

Currently there are no formal processes or positions through which to manage research; and policies, processes and forms have been adapted from other states & territories. Investigator lead research approximate 20 projects per year, and there is an estimated six NT commercially sponsored clinical trials active in any given year with the majority of these in the clinical areas of cancer and cardiovascular disease. NT Cardiac, administers several clinical cardiovascular disease trials and there is also community controlled research with community funding to administer these Charles Darwin University and Menzies Research Institute lead research, and provide the HREC although governance oversight is largely the responsibility of the unit or community organisation undertaking the project.

NT Health initiatives

A framework for a clinical trials coordination unit is under development and is expected to be launched in August 2018.

Queensland

Queensland Health, Health Innovation, Investment and Research Office Research Management Policy aims to ensure that all research conducted by Queensland Health or in collaboration with hospital and health services and/or external entities required to be compliant with relevant legislation. The Queensland Health Good Clinical Practice (GCP) Standard Operating Procedures (2010) is intended to complement institutional and sponsor standard operating procedures and are to be used to guide clinical practice for the conduct of clinical trials.

Queensland Health Researcher User Guide (2010) outlines how to obtain ethical and scientific approval by an HREC and the research governance office. Scientific and ethical review is conducted by an HREC. The research governance component requires completion of a SSA at each participating site to determine the level of support and suitability of a research study to be conducted and completed at a site, whether that study is multi-centre or single-site. The Standard Operating Procedures for Queensland Health Research Governance Officers (Version 5, 2013) apply to the conduct of all human research that uses Queensland Health facilities, patients, staff, tissue and data (medical and personal records or information). This policy outlines how a research governance officer assesses legal, financial, regulatory and contractual issues in practice, and each hospital and health service should have appropriate research governance. This is consistent with the National Statement, Australian Code, NHMRC Research Governance Handbook, NHMRC: Guidance for the National Approach to Single Ethical Review of multi-centre research, the QLD Research Management Policy and the TGA. The research governance officer is expected to complete their assessment of a valid SSA application within 25 days.

The following privacy and confidentiality laws apply in QLD:

- *Information Privacy Act 2009 (QLD)*
- Information Standard 42A - Information Privacy Guidelines
- *Public Health Act 2005 (QLD) ('PHA').*

A researcher may make an application under the Public Health Act 2005 (QLD) to the chief executive of Queensland Health to be given access to information for research purposes. The application must clearly set out the purpose and methodology of the research, as well as how the privacy of any identified individuals will be protected. The application must also state the views of a HREC on the research. In deciding the outcome of any application the chief executive of Queensland Health will have regard to the opportunities the research will provide for increasing knowledge and improved health outcomes, as well as privacy of those individuals identified. The PHA requires that a researcher not disclose the above mentioned health information without the written consent of the individual identified, or in instances where the information is suitably de-identified.

The *Information Privacy Act 2009* specifically states that health agencies must comply with the Australian Privacy Principles. The Australian Privacy Principles require that a health agency must not use or disclose personal information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless:

- The information is health information and the use or disclosure is necessary for research, or the compilation or analysis of statistics, relevant to public health or public safety
- It is impracticable for the health agency to seek the individual's consent before the use or disclosure
- The use or disclosure is conducted in accordance with guidelines approved by the chief executive of the health department for the purposes of this subparagraph
- For disclosure, the health agency reasonably believes that the entity receiving the health information will not disclose the health information or personal information derived from the health information or
- The health agency reasonably believes that the use or disclosure is necessary to lessen or prevent a serious threat to an individual's life, health, safety or welfare or a serious threat to public health, safety or welfare.

The *Guardianship and Administration Act 2000 (QLD)* applies to the consent process. Following ethics approval and before commencing the approved research, where a person is over the legal age of consent but has impaired capacity to consent, written application to the Queensland Civil and Administrative Tribunal

must be undertaken by the researcher for either special medical research or clinical research. The research must relate to a condition which the adult has (or has a significant risk of being exposed to), or the research must be intended to gain knowledge in relation to that condition.

The *Child Protection Act (1999) (QLD)* protects a child under 18 years, and consent to medical treatment and specifies that the chief executive of the Department of Communities, Disability Services and Seniors may authorise a researcher to have access to information, or to contact a child (or family etc.) to ask if they would like to participate in the applicable clinical research). Common Law in relation to consent, and impaired capacity to consent, applies for those under 18 years.

Queensland Health Sector (Clinical Records) Retention and Disposal Schedule 2012 (QLD) and the *Public Records Act 2002 (QLD)* provide rules for data retention, storage, disposal and archiving and Queensland Health is required to make and keep full and accurate records of its activities under the *Public Records Act 2002 (QLD)*. These records may be transferred to the archives if they are over 25 years old. In relation to specific health records for clinical research, records must be retained for 15 years from completion of research and 10 years after last patient/client service provision. Where there is no direction under the schedule then the research should follow Commonwealth requirements. Clinical research records for minors must be retained for 15 years from patient/client attaining 18 years of age; and 10 years after last patient/client service provision or medicolegal action.

Queensland Health recommends the use of the Medicines Australia CTRAs, and for research involving medical technologies, the Medical Technology Association of Australia clinical investigation research agreement and standard indemnity form. All commercially sponsored research must include the Medicines Australia Standard Form of Indemnity for Clinical Trials. Research that is not commercially sponsored and involves collaboration with an external organisation must also provide assurances of indemnity. Where appropriate, this may be included within the CTRA. All commercially sponsored research must provide evidence of appropriate insurance before research governance authorisation can be given. Other external collaborators may also be required to provide evidence of current insurance appropriate to the type of research.

The Research Management Policy Queensland Health, Health and Medical Research, Preventive Health Unit (2013) provide the standard operating procedures for Queensland Health HREC administrators for uploading all studies into AU RED. There is a Database of Research Activity (DoRA) which is a publicly accessible, searchable internet website that extracts and automatically downloads research data from AU RED and presents it in a format to allow researchers and other interested public stakeholders to search for and view summary level information about research being conducted in Queensland Health. The Standard Operating Procedures for Queensland Health Research Governance Officers (2013) provides the guides for navigating this database. More recently, a new via work-flow system ERM, has been implanted in Queensland and all research associated with public health institutions must be submitted to a lead HREC through this system.

Risk assessment and monitoring of research is dependent on the level of risk associated with a clinical trial and is undertaken by the HREC and RGO. It may include annual reports for all approved research, due on the anniversary of the HREC approval as well as:

- Resource utilisation
- Contract management
- Data Safety and Monitoring Board (DSMB) reports (or other nominated safety committee)
- Risk Assessment Report, based on the Queensland Health Risk Management
- Framework and Risk Management Policy may be required for investigator initiated research
- Reporting of serious adverse events (SAE) or serious unexpected suspect adverse reactions (SUSARs).

Queensland Health is a signatory to the NMA. A single ethics review process means one ethics approval for many sites. To obtain the regulatory approval for the commencement of a clinical trial, the TGA is notified via the CTN scheme after ethics approval. Within Queensland Health the median time for ethics review is 21 calendar days, after this the site can start once their clinical trial contract is signed. The overall process of research governance takes 103 median calendar days in Queensland. The HREC application fee for a commercially sponsored trial in Queensland public health services approximates $3,300, with an additional $3,300 per site for SSA.

Queensland Health initiatives

Queensland Health has established the Brisbane Diamantina Health Partners, an AHRTC with research ethics and site governance streamlining as a key focus of its strategic plan. Like NSW and the ACT Queensland Health implemented a new work flow system and data reporting platform, ERM. Queensland Health has undertaken a number of initiatives including:

- Leading the pilot of the 'tele-trials' which applies tele-health strategies to conduct a clinical trials in partnership with Quintiles, MTP connect and Clinical Oncology Society of Australia
- Consultation on approaches to site-specific governance processes for local site review of clinical trials was undertaken to determine volume and type of research occurring in Queensland hospitals and a review to determine the process for consenting patients to research who were impaired or too ill to consent
- A project to establish acceptance of the CTRA for South Eastern Border States, in collaboration with the Medicines Australia, the CTPRG and the Clinical Trials Forum
- Encouraging support for clinical trial networks including ACTA and cooperative trial groups.

South Australia

South Australia Research Governance Policy Directive (2016) outlines the research governance requirements applicable to research being undertaken across the South Australian public health system including regional health services, hospitals, community health services and public health clinics.

The state public sector in South Australia does not currently have a legislative privacy framework. However, South Australian government agencies are required to comply with a set of Information Privacy Principles and Information Privacy Principles Instruction. The Privacy Committee of South Australia oversees the implementation of these Information Privacy Principles by the South Australian public sector.

In addition, the South Australian Department of Health and Department of Families and Communities have developed a Code of Fair Information Practice which outlines what the Departments and their service providers should do, and what clients can expect, in relation to protecting personal information.

The Code of Fair Information Practice also has its own set of privacy principles which have specific requirements for the handling of health information. The following legislation applies to the consent process in SA:

- *Guardianship and Administration Act 1993 (SA)*
- *Consent to Medical Treatment and Palliative Care Act 1995 (SA)*
- *Advance Care Directives Act 2013 (SA).*

There is no South Australian legislation that specifically refers to or directly deals with the giving of consent for an adult who lacks the capacity to provide consent to participate in a human research project or a clinical trial. However, regarding medical treatment, a person of or over 18 years, of age if of sound, mind may give a direction under this section about the medical treatment a person wants or does not want. Where it is proposed to administer medical treatment to a patient with impaired decision-making capacity in respect of a decision that is required in relation to the medical treatment, a consent given by a person responsible for the patient to the administration of the proposed medical treatment.

The Consent to *Medical Treatment and Palliative Care Act (1995)* has provisions for the consent of minors, and a person of or over 16 years of age may make decisions about his or her own medical treatment as validly and effectively as an adult. A medical practitioner may administer medical treatment to a child if:

- The parent or guardian consents or
- The child consents and
- The medical practitioner who is to administer the treatment is of the opinion that the child is capable of understanding the nature, consequences and risks of the treatment and that the treatment is in the best interest of the child's health and well-being
- That opinion is supported by the written opinion of at least one other medical practitioner who personally examines the child before the treatment is commenced.

The *State Records Act 1997 (SA)* provides for retention and disposal of records held by public sector agencies, and the Information Privacy Principles provides the steps an agency should take to reasonably ensure that personal information in its possession or under its control is securely stored and is not misused. SA Health Record Management Policy Directive states that SA Health staff must transfer or dispose of a health record in compliance with the State

Records General Disposal Schedule - Clinical and Clinical-Related Records of Public Health Units in South Australia (Aug 2014), Adequate Records Management Framework and any other pertinent SA Health policies. Any personal information regarding a person involved on proceedings under this Act cannot be released for research purposes. It can only be released in aggregate form e.g. the presentation of statistics.

SA uses the Medicines Australia CTRAs and all clinical trials must be adequately insured and indemnified prior to their commencement at a SA public health organisation. To enable a SA public health organisation to assess whether the insurance and indemnification arrangements are satisfactory for a proposed research project or clinical trial, the principal investigator must contact the SA Health Research Governance Office/r responsible for the site/s where the research is to be conducted and provide them with the following documents as part of the Site-Specific Assessment (SSA) submission:

- Confirmation of Ethics Approval from a SA Health or certified NMA HREC
- A completed Site-Specific Assessment form, including relevant attachments, and (where requested) the HREC approved ethics application form
- Participant Information Sheet and Consent Form.

For sponsored research, including clinical trials, a third party sponsor insurance certificate of currency is required. The Medicines Australia Form of Indemnity completed and signed by the Sponsor, appropriately identifying the public health organisation/trial site, and for investigator-driven clinical trials involving external organisations (e.g. universities or research institutes), proof of indemnity, including current certificates of insurance may also be also be required. The level of monitoring of approved research projects undertaken by the HREC and organisation through the RGO is required to be aligned with the risk profile of the project and specific ethical, research governance, legislative and regulatory requirements that underpin the research.

The commercial sponsor HREC application fee: $5,500 with an additional SSA review fee $330. SA is a signatory to the National Mutual Acceptance Scheme and an SSA for each organisation/LHN must be submitted to the relevant RGO via Online Forms at the same time as the HREC application.

South Australian Health Initiatives

Adelaide Biomed City is a new biomedical precinct in Adelaide which brings together research, education and clinical care. The precinct contains the South Australian Health & Medical Research Institute (SAHMRI) and the new Royal Adelaide Hospital. All current clinical trials have moved to the new site, which was more aligned with many participants' views of the importance of integrating clinical care and clinical trials.

SAHMRI Clinical Research Platform (SCR) offers site coordination for clinical trials and provide resources for clinical trials, collects and reports operational metrics The NHMRC AHRTC – the SA Academic Health Science and Translation Centre has established a subcommittee to consider processes to improve efficiency in the conduct of clinical trials. SAHMRI is currently undertaking a review of research governance (site-specific) approval processes.

Key initiatives underway in South Australia being led in partnership with the South Australian Government Department of Health are:

- Clinical Trial Liaison Officers in the Local health Networks to provide:
  - a primary point of contact for trial sponsors and CROs to clinical trial units
  - support for all clinical trial processes
- Partnership with Sponsors and Clinical Research Organisations through:
  - regular meeting schedule with sponsors and CROs
  - engagement in new initiatives
- Communication with clinical trial staff via:
  - a portal for core documents
  - regular meetings and communication with trial unit staff
- Capabilities document for each unit to support feasibility assessment
- Recruitment strategies via website and hospital advertising
- Development of higher performing clinical trial staff through:
  - GCP training
  - protocol development
  - engagement of SA Health to ensure clinical trials are viewed as a part of routine clinical care
  - collaboration and partnerships with AHRTCs, networks and trial sites
  - streamlined HREC review and approval process through standardised guidelines for HREC application

- Budget support tools such as:
  - guidelines for negotiating budgets and site budget templates
- New IT platform and data management systems
- Standard third party provider templates for clinical trial agreements.

Victoria

The Victorian Department of Health, through the Department of Health and Human Services Centre for Evaluation and Research provides guidance to assist all sectors involved in clinical trials to understand the process to meet the regulatory requirements for clinical trial research in Victoria. In Victoria, research governance review considers legal compliance, financial management, accountability and risk management associated with research. HREC and SSA applications are registered via AU RED which is managed by the Victorian Department of Health (2014). The Research governance and site-specific assessment: Process and practice is a practical guide for RGOs to assist all stakeholders involved in clinical trials to understand the processes required to meet the regulatory requirements for clinical trial research in Victoria. The document includes the interface between research ethics and governance and a specific section on research governance.

Although the management of the HREC and SSA process is undertaken by the health networks, Victoria's Health and Medical Research Strategy 2016-2020 established its key priorities in the field of health and medical research, including actions to streamline its clinical trials processes. As in Queensland, the ERM workflow system must be used to complete and submit the HREC and SSA applications. The fee schedule for an HREC application in Victoria varies from $770 - $7,700 and $770 - $7,700 for an SSA submission.

Although the Victorian Department of Health and Human Services Centre for Evaluation and Research is a signatory to the NMA, completion of the Victorian Specific Module is to be submitted with the HREA. This is to ensure Victorian legislative requirements prior to HREC review of a clinical trial have been met. These requirements, such as compliance with the privacy legislation are set out under the *Health Records Act 2001 (VIC)* and the *Privacy and Data Protection Act 2014 (VIC)*. Under these Acts individuals have a legally enforceable right of access to health information about them that is contained in records held in Victorian health services. The Health Privacy Principles also apply to health information collected and handled in Victoria by the Victorian public sector and the private sector. The access regime and the Health Privacy Principles are designed to protect privacy and promote patient autonomy, whilst also ensuring safe and effective service delivery, and the continued improvement of health services. There are two Acts in Victoria that provide the legal requirements relating to consent and impaired capacity to consent:

- *Medical Treatment Planning and Decisions Act 2016 (VIC)*
- *Mental Health Act 2014 (VIC).*

These Acts require that, a medical research practitioner must not administer a medical research procedure to a person who does not have decision-making capacity in relation to the procedure unless consent has been obtained. Consent may be obtained through an instructional directive or from the person's medical treatment decision maker. Additionally, there is no requirement under the Acts to submit any research proposal to the Victorian Civil and Administrative Tribunal. There are two Acts that govern the consent of minors in Victoria:

- *Medical Treatment Planning and Decisions Act 2016 (VIC)*
- *Human Tissue Act 1982 (VIC).*

Under the Human Tissue Act (1982) a child is defined as a person who has not attained the age of 16 years. Under the *Medical Treatment Planning and Decisions Act (2016)* children can write an advance care directive which must be respected. If a child does not have decision-making capacity, their medical treatment decision maker will be a parent, guardian or other person with parental responsibility. A person (including a child of any age) has decision-making capacity to make a decision regarding clinical trials if the person is able to do the following:

- Understand the information relevant to the decision and the effect of the decision
- Retain that information to the extent necessary to make the decision
- Use or weigh that information as part of the process of making the decision
- Communicate the decision and the person's views and needs as to the decision in some way, including by speech, gestures or other means.

Victoria accepts the Medicines Australia CTRAs, and the Medicines Australia form of indemnity for clinical trials conduct for each participating site or, the Medical Technology Association of Australia form of indemnity for medicines and devices. In Victoria, state-wide insurance is provided through the Victorian Managed Insurance Authority and clinical trials must have a certificate of currency for public and products liability insurance from a commercial sponsor. The certificate of currency must:

- Specifically name the Australian corporate entity acting as commercial sponsor, or if using the global entity name, then the global entity must provide a letter to say the local entity is wholly owned and a named insured under the relevant insurance policy
- Cover the conduct of the relevant clinical trial in Australia
- Be current throughout the entire period in which the clinical trial is conducted
- Not have a defined statute of limitations
- Have acceptable deductibles and level of indemnity
- Have a limit of liability per claim and in the annual aggregate of $20 million for New South Wales and $10 million for other jurisdictions in Australia
- Ensure the excess deductible is no greater than $25,000 for each and every claim or series of claims arising out of one originating cause.

The *Health Records Act 2001(VIC)* provides the legislative requirements for data retention, storage, disposal and archiving.

Victorian Health initiatives

Victorian Department of Health through the Department of Health and Human Services Centre for Evaluation and Research are developing a toolkit to equip HRECs, researchers, sponsors and expert scientific reviewers to perform high quality review for early phase clinical trials. The toolkit is due for release in the third quarter of 2018.

Interview participants referred to the Royal Melbourne Hospital's Memorandum of Understanding with 11 partner organisations to streamline and harmonise ethical and governance review of all multi-centre human health research[6] as a beneficial model. In particular, access to weekly HREC review and a coordinated centrally located Research Support Service were commended.

The Victorian-based AHRTCs (Monash Partners Academic Health Science Centre and Melbourne Academic Centre for health) has been established and is undertaking a range of research programs in line with priority areas, including:

- VIC Health web-link has all clinical trial research processes including, SSA research SOP process and practice handbook
- Hospitals processes and policies (non-Gov.) not tracked by Department of Health
- Nothing unique in Victoria compared with other states and territories
- AHTECs work collaboratively not funded through health department
  - Monash Partners Academic Health Science Centre
  - Melbourne Academic Centre for health
- Developing processes and sites to conduct early phase trials with the TGA and sponsor companies due for release in August
- Strategic Plan – for Health & Medical Research in Victoria.

Western Australia

Department of Health, Western Australia (2016) Research Policy Framework specifies the research requirements with which all Health Service Providers (HSPs) must comply in order to ensure effective and consistent research activity across the WA health system. It includes legislative/policy/codes and national best practice guidelines, and consistent management of research governance and IP across WA. The Western Australia Research Policy Framework specifies the research requirements that all Health Service Providers must comply with in order to ensure effective and consistent research activity across the WA health system. Under this policy framework all Health Service providers and the Department of Health must comply with all mandatory requirements related to the WA Health Research Governance Framework.

WA Health is a signatory to the NMA and the following ethics application forms are available for electronic completion via the Research Governance work-flow system (RGS):

- Western Australian Specific Module (WASM) - must accompany the HREA or
- WA Health Ethics Application Form (WAHEAF).

The NHMRC HREA is not available electronically in RGS. Governance forms are available for electronic completion and submission via RGS to WA Health research governance offices including:

- WA Health Site-Specific Assessment (SSA) Form and Budget Form
- WA Health Access Request Form
- WA Health Declaration of Confidentiality
- WA Health Research Conflict of Interest Form.

The Western Australia Health Research Governance Policy and Procedures (2012) applies to human research conducted by WA Health or its employees using participants, tissue or data obtained through WA Health. This policy promotes governance standards that comply with relevant national and state legislation, guidelines and codes of conduct.

The Western Australia Health National Mutual Acceptance Guidelines (2017) provides guidance on the National Mutual Acceptance scheme for ethical and scientific review for multi-centre research projects conducted in public health organisations. It involves a process of research governance review/institutional authorisation/ site-specific assessment which must be undertaken by a participating public health organisation site.

The Western Australia Health Research Authorisation and Monitoring Forms Guidelines (2017) provides guidance regarding the Research Governance Service information technology system which has been developed to support the WA Health research governance framework and allow WA Health to participate in national initiatives, including the NMA process and measuring and reporting to the National Aggregated Statistics for Clinical Trials.

The Western Australia Health Single Ethical Review Standard Operating Procedures (2013) provides standard operating procedures that apply to the conduct of human research conducted within WA Health by WA Health employees and non-WA Health employees who propose to undertake, manage, review and govern human research and/or involving participants, their tissue or data accessed through WA Health. All human research conducted in WA Health must undergo local site governance review before authorisation can be granted.

As per the Commonwealth requirements; and WA guidelines, information must be used and disclosed for research in accordance with the *Health Services Act 2016 (WA)* and Information Use and Disclosure Policy (2017).

Under the *Public Sector Management Act 1994 (WA)*, WA Health employees must comply with the WA Health Code of Conduct to maintain confidentiality of personal or other information. External research personnel who will be either conducting a research project within WA Health or accessing WA Health participants, their tissue or data for a research project must submit the WA Health Declaration of Confidentiality and/ or the Student Research and Confidentiality Declaration with the WA Site-Specific Assessment Form. WA Health encourages the use of NHMRC standard Participant Information Consent Forms (PICFs).

The state public sector in WA does not currently have a legislative privacy regime. Various confidentiality provisions cover government agencies and some of the privacy principles are provided for in the *Freedom of Information Act 1992 (WA)* and overseen by the Office of the Information Commissioner (WA). The Health and Disability Services Complaints Office is an independent statutory authority that also handles complaints relating to health and disability services in Western Australia.

There is no legislation that specifically refers to the giving of consent by a person with impaired capacity to participate in a clinical trial. The Guardianship and *Administration Act 1990 (WA)* does not include a provision for consent by a substitute decision maker for a person to participate in medical research. Consent under the Guardianship and Administration Act 1990 (WA) may only be provided by a substitute decision maker for a person to participate in treatment which is in the best interests of the patient. Consent to treatment under this Act can be given by the patient if the patient has made an appropriate advance health directive, by an appointed enduring guardian, a guardian, or another responsible person. Once the provisions of the Act have been satisfied such that the research is treatment which is in the best interests of the patient and the appropriate substitute decision maker under the Act has been identified, then the guidelines in the National Statement have application.

If the research project intends to recruit persons in WA who may be deemed incapable (either mentally or physically) of providing consent the investigator will be required to provide the reviewing HREC with sufficient details to make an assessment of whether the provisions of the Act and the ethical requirements set out in the National Statement have been met. This must be documented in the Western Australian Specific Module (WASM) which accompanies the Human Research Ethics Application (HREA). Within the Mental Health Act 2014 the definition of a 'mental health service' and 'relevant information' applies to medical or epidemiological research related to mental illness. The provisions of the Act must be considered when disclosing relevant information.

The *Age of Majority Act 1972* allows persons aged 18 years or more to have full legal capacity. Researchers must address in the HREA and the WASM how the recruitment of children and/or young people (under 18 years of age) will be managed:

- *Age of Majority Act 1972 (WA)*
- *Working with Children (Criminal Record Checking) Act 2004 (WA)*
- *WA Health Consent to Treatment Policy.*

Generally, parents may authorise treatments on behalf of their children, where the treatment is in the child's best interests. However, as a child gets older, if they are assessed as having sufficient intellectual and emotional maturity and competence to understand information relevant to a proposed treatment, including its risks, benefits and alternatives then they are able to provide consent.

A Working with Children Check is required by a person if they engage in child-related work. This must be addressed in the WA Site-Specific Assessment Form. State Records Act 2000 (WA) Section 19, requires that every government organisation must have a Recordkeeping Plan. The WA Health Recordkeeping Plan documents suitable security arrangements for storage of paper-based and electronic information for all types of records (patient, administrative, financial, human resource management). The Patient Information Retention and Disposal Schedule 2016 (Index No. 5.7) covers research records related to patient/subject records, consent and research requests.

Western Australia Health initiatives

In July 2016, the *Health Services Act 2016* was introduced to create health service providers as statutory authorities. Health service providers are in the process of establishing centralised research governance units.

It was also noted that the AHRTC in Western Australia, the Western Australian Health Translation Network[7] (WAHTN), is working closely with WA Health and others to improve the efficiency and effectiveness in the conduct of clinical trials. To this end, WA's Research Governance Service information technology system supports the standardisation of governance processes IT web-based on-line forms for NMA signatories (3,000+ users 1,500 projects), and the Clinical Trials and Data Training Centre. This platform provides a central point of contact for clinical trial sponsors and on-line GCP training free to members training via four on-line learning modules.

Under the Council of Australian Governments Health Council budget measure, four roles, providing central points of contact have been established to work across the four major health services - North Metro, East, South and Child and Adolescent Health (remote WA is covered by WA Country Health Service) and standard operating procedures have been developed for some parts of the clinical trial process developed and implemented as an operational directive by WA Health and local trial sites determine their own standard operating procedures based on these. WA Health also contributes to national clinical trial operational reporting via the National Aggregate Statistics.

WA Health have agreed to establish permanent staff positions and standardised job descriptions for clinical trial site staff and staff training is provided through the on-line learning modules on the Clinical Trials and Data Training Centre platform.

WA uses an older version (2009) of the Medicines Australia Standard Agreement, which is similar, but has been amended and a number of clauses removed including those around improper payment, modification of agreement and press statements. WA Health insurance requirements are contained within the schedules of the clinical trial research agreements and outlined in the *WA Health Research Governance Policy and Procedures 2012 (OD 0411/12)*.

For commercially sponsored research projects, the sponsor is required to provide indemnity for both the site and the HREC providing the ethical review. Links to the Medicines Australia indemnity forms can be found on their local WA Health site. The following sets out the indemnity arrangements applying to HRECs in respect of commercially sponsored projects:

- Project not conducted within health service provider: the health service provider's HREC provides ethical review for commercially sponsored projects to be conducted at sites not under the control of the HSP. Hence, the health service provider provides only the HREC review. It is the health service provider's responsibility for ensuring that its HREC is indemnified by the sponsor by way of the MA HREC Review Only Form of Indemnity
- Project conducted only within the health service: the health service provider's HREC provides ethical review for commercially sponsored project to be conducted only at sites under the control of the health service provider. It is the health service provider's responsibility for ensuring that its HREC is indemnified by the sponsor by way of the MA Standard Form of Indemnity
- Project conducted within and outside of health service provider: the HREC provides ethical review for commercially sponsored project to be conducted by both sites under its control and sites not under its control. The health service provider is responsible for ensuring that its HREC is indemnified by the sponsor by way of the MA Standard Form of Indemnity
- Ethical review not conducted by health service providers HREC: the health service provider proposes to conduct a commercially sponsored project and the ethical review is provided by an HREC external to the health service providers. The health service provider is not responsible for ensuring that the external HREC is indemnified by the sponsor. The health service provider is only responsible for ensuring that its site is indemnified by the sponsor by way of the MA Standard Form of Indemnity.

Fees schedules for HREC and SSA review are available via the Ethics Office Ethics Executive Officers (EEOs) and RGOs respectively. Western Health Ethics & Governance Review has its own fee schedule (via Office for Research).

This schedule details the fees for commercially sponsored research projects, investigator-initiated/collaborative group with no commercial involvement and quality assurance and low/negligible risk projects are available from individual RGOs.

WA Health Research Governance Service (RGS) Information Technology (IT) System supports the workflow and reporting required for research governance processes. All details on the ethics and governance submission can be electronically downloaded into the RGS IT system for processing and review by the Ethics Executive Officer, HREC, RGO and the site. Ethics and Research Governance Offices manage and track research projects utilising the system. This provides a single platform, with automatic data import capabilities, for investigators to complete HREC and Research Governance applications online and upload documents, as well as monitor the progress of their application.

WA Health have also developed guidelines for human biobanks, genetic research databases and associated data that provide principles and best practices for the establishment, governance, management and use of human biobanks, genetic research databases and associated data used for research purposes.

The financial tracking spreadsheets developed by WA Health for use by trial sites to track income vs costs contain in-built calculations including costs for salaries, time, participant activity pricing and patient costs that apply the IHPA costs structure for clinical trials. There is ongoing support for an update of the IHPA cost structure to be applied. There are also templates for proposed financial schedules, cost structures and processes to assist trial managers and trial investigate to negotiate sponsor contracts for negotiating contracts with trial sponsors. WA Health is also trialling a model for business unit support services, capturing data from the costing tool for activity based funding (fee for service) and considering implementing a block funding schedule to support clinical trial service provision.

Summary

The mapping exercise details current regulation, legislation and guidance material with which clinical trials must comply at the national level and within each state and territory. Interviews with key stakeholder groups have provided key insights into the drivers for change across the clinical trial landscape in Australia and capture initiatives currently underway to improve the operating environment across the public and private health sectors.

Interview participants identified process and policy variation across, and sometimes within, jurisdictions, as having a negative impact on the timeliness and quality of review process and there was limited awareness of how jurisdictional policies and processes align with national regulation, legislation and guidance material. Confusion remains across the public and private health care sector regarding the definition of governance and the role and function of the research governance office. Several interview participants were of the view that fewer clinical trials were being conducted in Australia as a result of unwarranted variation in costs and trial administration. A minority of participants questioned this view and referred to a report by MTP Connect that indicates that the Australian clinical trials sector is growing at roughly 5% per year.[8]

All interview participants identified significant improvement in ethics review processes have been realised through the NMA scheme, although they proposed additional opportunities to streamline processes remain. For example, the lack of acceptance of the NMA across the public, private and university sectors was considered the largest single barrier to timely and streamlined HREC review and approval. Participants suggested national standard operating procedures for ethics committees and an audit of the quality of HREC review is needed to provide consistency of HREC review across the public and private sectors. Participants preferred a single national SSA form and concurrent review of HREC and SSA applications as the way forward to a streamlined pre-approval process.

Participants agreed that standard operating procedures have the potential to improve workflow and consistent workforce arrangements through tenured positions, site staff training and certification may improve the capacity for trial sites to engage a skilled and reliable workforce and reduce high staff turnover rates currently experienced.

The benefits of clinical trials to patients were universally acknowledged and, to invigorate the clinical trial environment, participants expressed universal support for the development of the National Clinical Trials Governance Framework. Participants reported that standards rather than standardisation would provide consistent understanding of quality processes and measures of operational performance. Participants agreed however that processes could, and perhaps should, be standardised in the future. Participants considered the essential elements of a framework would have applicability across all research sectors; provide standards and the means to enforce them through accreditation and provide the delineation of roles and responsibilities for all parties to increase workforce capability and capacity.

Appendix 1

The mapping exercise guide for discussion included the following:

1. Could you please tell me about your role at [name of organisation]?
2. Could you broadly describe the ways in which [name of organisation] is involved in the conduct of clinical trials?
3. Which individuals / branches / divisions / organisations do you most have contact with regarding clinical trials? Who do you consider to be a key stakeholder?
4. Based on your understanding, what clinical governance policies and processes are currently in place or in development to oversight clinical trials in Australia? Anything else?
5. What do you think could be done, if anything, to improve and/or streamline these policies and processes? Anything else?
6. Could you outline the ways in which clinical governance policies and processes for clinical trials differ across Australian jurisdictions? What do you think is the impact of this variation?
7. [probe for consistency in timelines, election of HREC officers, approval processes etc]
8. How well do you think jurisdictional clinical policies and processes align with those at a national level? What is the impact of variation?
9. Could you tell me about any local initiatives you are aware of that make the conduct of clinical trials more efficient?
10. [Probe for public and private sector initiatives]
11. How do you think a national Clinical Trials Governance Framework could contribute to improving or streamlining approval processes for clinical trials in Australia?
12. What factors do you think should be considered in the development of a National Clinical Trials Governance Framework? Anything else?
13. How would you measure the success of a National Clinical Trials Governance Framework? Anything else?
14. Is there anything else you would like to share that could inform the development of the National Clinical Trials Governance Framework?

Appendix 2

Australian reports and guiding documents identified during the search of grey literature

Clinical trial initiatives

Akister & Mepham (2015) Vocational Education and Training (VET) *for NHMRC.*

Australian Government, Medical Research Future Fund (2015) *Australian Medical Research and Innovation Strategy 2016–2021*.

Clinical Trials Action Group (2011) *Clinically Competitive: Boosting the Business of Clinical Trials in Australia*.

Howard J (2015) Translation of Research for Economic and Social Benefit: Measures that facilitate transfer of knowledge from publicly funded research organisations to industry. *Report for Securing Australia's Future Project*. Translating research for economic and social benefit: country comparisons– on behalf of the Australian Council of Learned Academies.

NHMRC (2015) C*linical Trials Ready: An NHMRC concept to recognise clinical trials sites that are 'ready, willing and able' to conduct clinical trials*. Report of a national consultation, November 2015.

NSW Ministry of Health, Office for Health and Medical Research (2014) NSW Health and Medical Research Hub Strategy 2014–2019.
http://www.health.nsw.gov.au/ohmr/Pages/hub-strategy.aspx

South Australia Department of Health (2017) Research Focus 2020: Our Strategic Priorities
http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/resources/research+focus+2020

Victorian Department of Health (2016) Healthier Lives, Stronger Economy – Victoria's Health and Medical Research Strategy 2016–2020.

Western Australian Department of Health (2015) WA Health Strategic Intent 2015–2020
http://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/About%20WA%20Health/wa_health_strategic_intent14052015.pdf

Research ethics and governance landscape

Ali Khan O (Medicines Australia), Maccarrone C (GlaxoSmithKline), Jones A (Boehringer Ingelheim), Deborah Monk D (Medicines Australia), Nielsen L (Sanofi) (2013) *Survey of Research Governance Timelines in Australia*.

Doran E, Fleming J, Ian Kerridge I, Stewart C; Centre for Values, Ethics and Law in Medicine at the University of Sydney (2015) for NSW Health Department. *Clinical ethics support literature review*
https://www.health.nsw.gov.au/clinicalethics/pages/default.aspx

Health Consult Pty Ltd (2014) for the National Health and Medical Research Council. *National Consultation on a 'Good Practice' Process for the Governance Authorisation of Clinical Trials.*

Clinical trials/research governance – operational

National

Guidelines for Ethical Research in Australian Indigenous Studies (2012)
http://aiatsis.gov.au/sites/default/files/docs/research-and-guides/ethics/GERAIS.pdf

Australian Government, Clinical Trials Jurisdictional Working Group (2015-6) *Second Activity Report on Clinical Trials in Australian Public Health Institutions 2015-6*.
http://www.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials

Australian Government, National Health and Medical Research Council Report v2.3 (2016) *Good Practice Process for Site Assessment and Authorisation Phases of Clinical Trial Research Governance.*

Australian Government, National Health and Medical Research Council and the Therapeutic Goods Administration (2016) *Safety monitoring and reporting in clinical trials involving therapeutic goods.*

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

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

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

Australian Government, National Health and Medical Research Council (2018) *Supplementary guidance for Safety monitoring and reporting in clinical trials involving therapeutic goods.*

Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria, Western Australia – National Mutual Acceptance Single Ethical Review of Multi-centre Human Research Projects (2017) *National Mutual Acceptance Single Ethical Review of Multi-centre Human Research Projects Brochure*
https://rgs.health.wa.gov.au/Documents/NMA%20Brochure.pdf

Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria, Western Australia National Mutual Acceptance Single Ethical Review of Multi-centre Human Research Projects (2017) *Monitoring and Reporting Framework*
https://rgs.health.wa.gov.au/Documents/NMA%20Monitoring%20and%20Reporting%20Framework.pdf

Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria, Western Australia-National Mutual Acceptance Single Ethical Review of Multi-centre Human Research Projects (2017) *Monitoring and Reporting Tables*
https://rgs.health.wa.gov.au/Documents/NMA%20Monitoring%20and%20Reporting%20Tables.pdf

Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria, Western Australia National Mutual Acceptance Single Ethical Review of Multi-centre Human Research Projects (2018) *Standard Principles for Operation*
https://rgs.health.wa.gov.au/Documents/NMA%20Standard%20Principles%20for%20Operation.pdf

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

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) *ICH Harmonised Guideline Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)*. Current Step 4 version dated 9 November 2016. Replaces: Note for guidance on good clinical practice (CPMP/ICH/135/95)
https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

National Health and Medical Research Council (2016) *Good Practice Process for Site Assessment and Authorisation Phases of Clinical Trial Research Governance v2.3*.

National Health and Medical Research Council (2016) *Safety monitoring and reporting in clinical trials involving therapeutic goods*.

National Health and Medical Research Council (2016) *Streamlining the site assessment and authorisation of Clinical Trials: Final Report*.

National Health and Medical Research Council (2015) *National Statement on Ethical Conduct in Human Research (2007) updated 2018*.

National Health and Medical Research Council (2014) *Laws and Rules relating to ethical review of research*.

National Health and Medical Research Council (2014) *Indemnity and Insurance Arrangements for Clinical Trials in the Public and Private Sectors in Australia*.

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

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Privacy and confidentiality:

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- Australian Privacy Principles
- NHMRC Guidelines approved under sections 95 and 95A of the Privacy Act
- Australian Institution of Health and Welfare Act 1987

Consent and impaired capacity to consent:

- Family Law Act 1975

Data retention, storage, disposal and archiving:

- Archives Act 1983

Other relevant legislation:

- Therapeutic Goods Administration Act 1989 and Regulations

Australian Capital Territory

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Legislation (ACT)

Privacy and confidentiality

- Health Records (Privacy and Access) Act 1997
- Public Health Act 1997

Consent and impaired capacity to consent:

Guardianship and Management of Property Act 1991

Medical Treatment (Health Directions) Act 2006

Mental Health (Treatment and Care) Act 1994

Powers of Attorney Act 2006

Powers of Attorney Amendment Act 2016

Children and Young People Act 2008

Information Privacy Act 2014

Data retention, storage, disposal and archiving:

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New South Wales Ministry of Health Research Ethics and Governance Information System (REGIS) online website.

Legislation (NSW):

Privacy and confidentiality:

Health Records and Information Privacy Act 2002

Privacy and Personal Information Protection Act 1998

Statutory Guidelines on Research

Consent and impaired capacity to consent:

Part 5, Guardianship Act 1987 (NSW)

Guardianship Regulation 2010 (NSW) PD2005_406 Consent to Medical Treatment

Data retention, storage, disposal and archiving:

State Records Act 1998 (NSW)

- General Retention and Disposal Authority: Public Health Services
- Patient/Client Records (GDA17) Administrative Records (GDA21)
- GDA17: Disposal classes 8.0.0 – 8.1.5 (Research Management) deal with records created for the management of the conduct of clinical and nonclinical research, trials or studies, etc. Disposal actions (including timeframes for retention) are listed against each disposal class
- GDA21: Disposal classes 15.0.0 – 15.6.3 (Research Management) deal with records created for the management of the conduct and operations of projects, programs, trials or studies conducted for the purposes of advancing medical knowledge
- Disposal class 5.3.3 deals with records relating to the establishment and meetings of ethics/ research committees
- Disposal actions (including timeframes for retention) are listed against each disposal class
- Health Privacy Principles also require data storage to be secure, and not kept longer than necessary

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https://www.health.Qld.gov.au/__data/assets/pdf_file/0029/156791/resrch_user_guide_v1.pdf

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Legislation (Qld):

Privacy and confidentiality:

Information Privacy Act 2009

Information Standard 42A - Information Privacy Guidelines

Public Health Act 2005 (Qld) ('PHA')

Consent and Impaired Capacity to consent:

Guardianship and Administration Act 2000

Child Protection Act 1999

Data retention, storage, disposal and archiving:

Queensland Health Sector (Clinical Records) Retention and Disposal Schedule (2012)

Public Records Act 2002

South Australia

South Australia (2016) *Research Ethics Operational Policy Directive*
http://www.sahealth.sa.gov.au/wps/wcm/connect

South Australia (2017) *SA Health Research Ethics and Governance Fees Structure*
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Legislation (SA)

Consent and Impaired Capacity to consent:

Guardianship and Administration Act 1993 (SA)

Consent to Medical Treatment and Palliative Care Act 1995

Advance Care Directives Act 2013 (SA)

Consent to Medical Treatment and Palliative Care Act 1995

Data retention, storage, disposal and archiving:

State Records Act 1997

Information Privacy Principles:

Records General Disposal Schedule No 28 – Clinical and Clinical-Related Records of Public Health Units in South Australia (Aug 2014), Adequate Records Management Framework and any other pertinent SA Health policies.

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Victorian Department Australian Research Ethics Database (AU RED) and Ethics Review Manager (ERM) online website.

Legislation (Vic):

Privacy and confidentiality:

Health Records Act 2001 (Vic)

Privacy and Data Protection Act 2014 (Vic)

Completion of the Victorian Specific Module, to be submitted with the HREA, will address Victorian legislative requirements for HREC review

Consent and Impaired Capacity to consent:

Medical Treatment Planning and Decisions Act 2016

Mental Health Act 2014.

Medical Treatment Planning and Decisions Act 2016

Human Tissue Act 1982 (Vic)

Tasmania

Idenfitying Cultural Barriers and Enablers to Conducting Clinical Trials Research in Tasmanina hospitals.

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Department of Publich Health and Community Medicine, Faculty of Medicine, UNSW.

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Legislation (Tas):

Privacy and confidentiality:

Personal Information and Protection Act 2004

Information Privacy Principles

Consent and Impaired Capacity to consent:

Guardianship and Administration Act 1995

Guardianship and Administration Regulations 2007

Data retention, storage, disposal and archiving:

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Western Australia

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Department of Health WA (2018) Research Governance Service: Adults with Impaired Capacity or Unable to Consent WA Specific information
https://rgs.health.wa.gov.au/rgshelp/Pages/WA%20Specific%20Information.aspx

Department of Health WA Health Translation Network (WAHTN)
https://www.wahtn.org/

Department of Health WA Research Education & Training Program (RETP)
https://www.wahtn.org/enabling-platforms/research-education-training-program-retp/

Department of Health WA Research Governance Service (RGS) online website
https://rgs.health.wa.gov.au/Pages/Home.aspx – (3500 users across Australia & 1220 projects since its launch in December 2016).

Legislation (WA):

Privacy and confidentiality:

Freedom of Information Act 1992
Health Service Act 2016
Public Sector Management Act 1994
State Records Act 2000

Consent and Impaired Capacity to consent:

Guardianship and Administration Act 1990
Mental Health Act 2014
WA Health Consent to Treatment Policy
Age of Majority Act 1972
Working with Children (Criminal Record Checking) Act 2004
WA Health Consent to Treatment Policy

Data retention, storage, disposal and archiving:

State Records Act 2000

Northern Territory

Legislation

Privacy and confidentiality:

- Information Act 2003
- Information Privacy Principles

Consent and Impaired Capacity to consent:

- Guardianship of Adults Act (NT)
- Guardianship of Adults Regulations (NT)
- Advance Personal Planning Act (NT)
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Other related documents

Management of Safety Information from clinical trials. Clinical Trials Report of CIOMS Working Group VI Geneva, 2005.

International Ethical Guidelines for Health-related Research Involving Humans Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) Geneva, 2016.

Bellbery Limited

http://bellberry.com.au/im-a-researcher/guidelines/policies-sops-guidelines/

- SOP001 How to apply
- Protocol Guidelines
- Participant Information Sheet Guidelines
- Informed Consent Guidelines
- Conduct of Identical Phase 3 Studies Guidance
- Guidance for Investigators on Conduct of Extension Studies
- On-Line CTN Scheme Guidance for Investigators
- Participant Documents – Version Control
- Multi-stage Phase 1 Studies in Healthy Volunteers

Policies

- POLICYI001 Administration Fees
- POLICYI002 Participant Payment and Reimbursement
- POLICYI003 Conflicts of Interest
- POLICY004 Adverse Events and Safety Reports
- POLICY005 Complaints Related to the Conduct of Research Projects
- POLICY006 Complaints Related to the Review Process
- POLICYI007 Ionising Radiation
- POLICY008 Advertising
- POLICYI009 Monitoring of Approved Trials
- POLICYI009a Site Monitoring
- POLICYI010 Monitoring Progress Reports
- POLICYI011 Data Storage and Retention
- POLICYI013 Pregnancy and Sexual Health
- P0LICYI014 Compensation
- P0LICYI015 Investigator Qualifications
- POLICYI016 Low Negligible Risk Research
- POLICYI017 Multi-Site Applications
- POLICYI018 Adult Photographic Release Form
- POLICYI019 Monitoring Protocol Violations
- POLICYI020 Monitoring-Withdrawal-Suspension of Ethical Approval
- POLICY021 Communication with Researchers
- POLICYI022 Governance of Research
- POLICYI023 Timeliness of Ethical Review
- POLICYI024 HREC Member Details
- POLICYI025 Confidentiality Privacy
- POLICYI026 Quality Assurance and Ethical Review
- POLICY027 Electronic Signature
- POLICYI028 Taking Over Ethical Oversight of Approved Research
- POLICYI029 National Approach to Single Ethical Review of Multi-Centre Research (National Approach

Appendix 3

National and jurisdictional documents describing roles and responsibilities for individuals and groups involved in the conduct of clinical trials.

	DOCUMENT
Australian government	NHMRC - National Statement on Ethical Conduct in Human Research (the National Statement 2007, updated, 2018) **https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018**
	NHMRC – Australian Code for the Responsible Conduct of Research **https://nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018**
	Good Practice Process (GPP) for the Site Assessment and Authorisation Phases of Clinical Trial Research Governance **https://www.australianclinicaltrials.gov.au/good-practice-process-site-assessment-and-authorisation-phases-clinical-trial-research-governance**
	TGA - Australian Clinical Trial Handbook 2018:Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods **https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdf**
NSW	Operations Manual: Research Governance Officers 2010 **https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2010_015.pdf**
	Research - Authorisation to Commence Human Research in NSW Public Health Organisations **https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2010_056.pdf**
WA	WA Health: Research Governance Policy and Procedures Nov 2012 **http://www.health.wa.gov.au/circularsnew/attachments/724.pdf**
QLD	Standard Operating Procedures for Queensland Health Research Governance Officers 2013 **https://www.health.Qld.gov.au/__data/assets/pdf_file/0026/147626/rgo_sop.pdf**
	Standard Operating Procedures for Queensland Health HREC Administrators 2013 **https://www.health.Qld.gov.au/__data/assets/pdf_file/0034/147598/hrec_sop.pdf**
	SOP – Investigator Responsibilities June 2010 **https://www.health.Qld.gov.au/__data/assets/pdf_file/0011/151004/gcp_sop10.pdf**
	SOP – Sponsor Responsibilities In Investigator Initiated Studies June 2010 **https://www.health.Qld.gov.au/__data/assets/pdf_file/0019/151183/gcp_sop11.pdf**
VIC	Victorian Department of Health (2014). Research governance and site-specific assessment: Process and practice **https://www2.health.vic.gov.au/about/publications/researchandreports/research-governance-and-site-specific-assessment-process-and-practice**
SA	Research Governance Policy Directive 2017 **http://www.sahealth.sa.gov.au/wps/wcm/connect/0fb971004aaf196b9a0dfa7633bbffe0/Directive_Research+Governance+Policy_v3_Jan2016.pdf**
ACT	ACT Health Research Committees – Terms of Reference **https://www.health.act.gov.au/research/about-the-office-of-research/**
	ACT Health Human Research Ethics Committee – Low Risk Sub-Committee Terms of Reference – June 2014 **https://www.health.act.gov.au/research/research-ethics-and-governance/low-risk**

List of abbreviations

Abbr	Full Term
ACAT	ACT Civil & Administrative Tribunal
ACTA	Australian Clinical Trials Alliance
ACRES	Alliance for Clinical Research Excellence and Safety
AEs	Adverse Events
AHREC	Aboriginal Health Research Ethics Committee
AHRA	Australian Health Research Alliance
AHRTC	Advanced Health Research Translation Centres
ANZCTR	Australian and New Zealand Clinical Trials Registry
APP	Australian Privacy Principles
CHC	Council of Australian Governments Health Council
CRG	Clinical Research Group
CTC	Health Clinical Trials Committee
CTJWG	Clinical Trials Jurisdictional Working Group
CTN	Clinical Trials Notification
CTRA	Clinical Trials Research Agreement
CTSC	Clinical Trials Sub-committee
CTU	Clinical Trial Unit
CTX	Clinical Trials Exemption
CTTI	Clinical Trials Transformation Initiative
CT:IQ	Clinical Trials: Impact & Quality
DHHS	Department of Health and Humans Services
DoH	Australian Government Department of Health
DSMB	Data Safety Monitoring Boards
EEO	Ethics Executive Officer
ECI	Eliminate Cancer Initiative
ERM	Ethical Review Manager
GABT	Guardianship & Administration Board of Tasmania
GCP	Good Clinical Practice
HIIRO	Health Innovation, Investment and Research Office
HMR	Health and Medical Research
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee
HSP	Hospital Service Provider
ICH-GCP	International Conference on Harmonisation (ICH) Good Clinical Practice (GCP)

Abbr	Full Term
IHPA	Independent Hospital Pricing Authority
ICMJE	International Committee of Medical Journal Editors
KPI	Key performance indicator
MACH	Melbourne Academic Centre for Health
MRFF	Medical Research Futures Fund
MRI	Medical research institute
MTAA	Medical Technology Association of Australia
NAS	National Aggregate Statistics
NCAT	NSW Civil and Administrative Tribunal
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
NMAJWG	National Mutual Acceptance Jurisdictional Working Group
NPP	National Privacy Principle
OHMR	Office for Health and Medical Research
PHO	Public Health Organisation
REGIS	Research Ethics and Governance Information System (NSW Health)
REGO	Research Ethics Governance Office
RGO	Research governance officer
RGS	Research Governance Service
RUG	Research User Guide
SAEs	Serious Adverse Events
SAHMRI	South Australian Health & Medical Research Institute
SHN	Speciality Health Network
SOP	Standard operating procedures
SEBs	South Eastern Border States
SSA	Site-specific assessment
SVHM	St. Vincent's Hospital Melbourne
TGA	Therapeutic Goods Administration
THS	Tasmanian Health Service
WAHEA	Western Australian Specific Module
WASM	Western Australian Health Ethics Application Form
WAHTN	Western Australian Health Translation Network
WHO	World Health Organization

References and Endnotes

1. The University of Tasmania is contracted by the Tasmanian Department of Health and Human Services to undertake this function in Tasmania.
2. Therapeutic Goods Administration **https://www.tga.gov.au**
3. St Vincent's Hospital Melbourne Research Valet® program **https://www.svhm.org.au/research/industry/research-valet**
4. PD2008_046 Policy Directive Ethical Review for External Entities **https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2008_046.pdf**
5. United Kingdom costing tool template **https://www.ukdaTaservice.ac.uk/manage-data/plan/costing**
6. Royal Melbourne Hospital's Memorandum of Understanding with partner organisations **https://www.thermh.org.au/research/researchers/about-research/streamlined-ethics-and-governance-review**
7. The Western Australian Health Translation Network **https://www.wahtn.org/**
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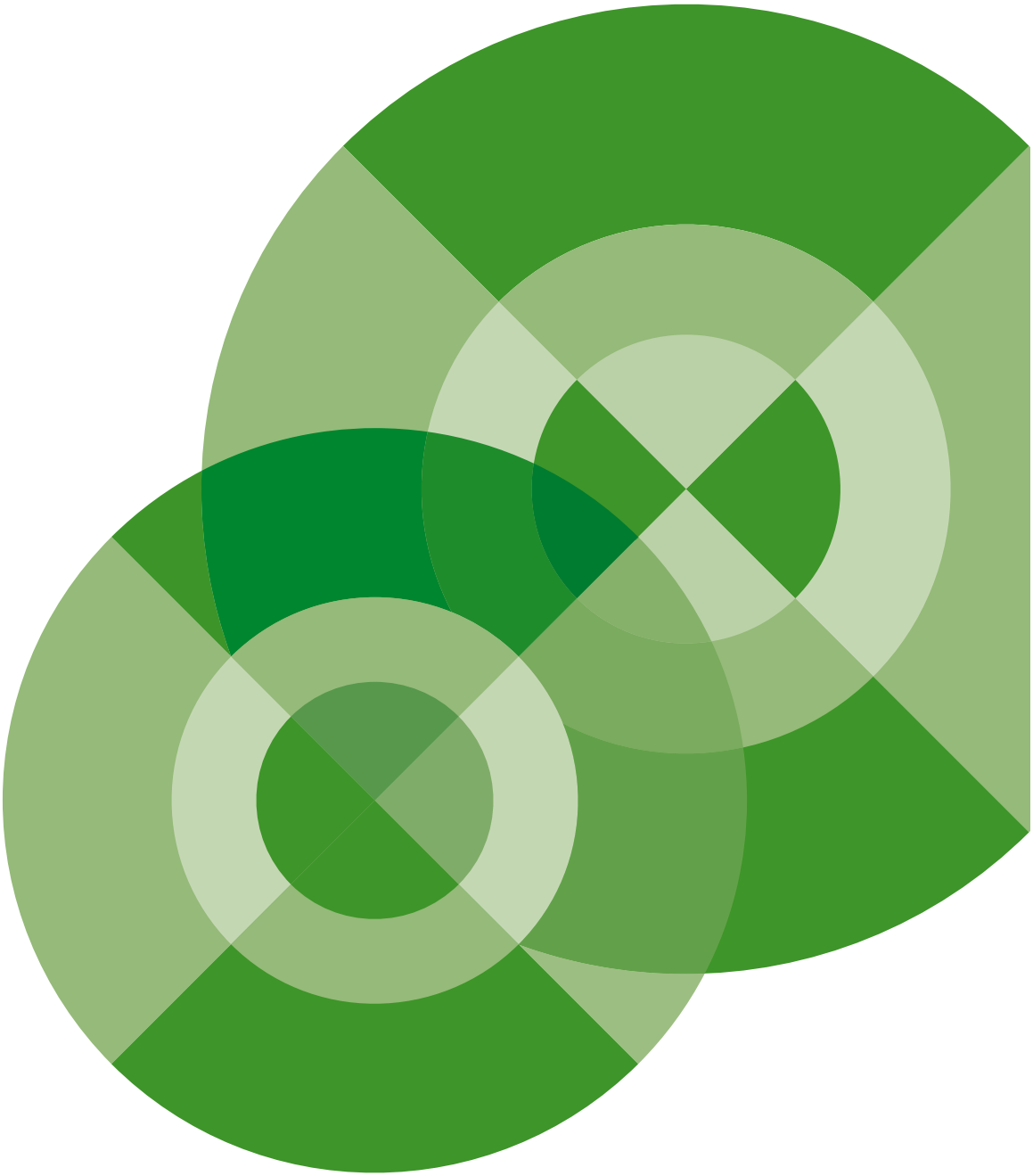

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