TRIM:D20-13683

May 2020

Legislation and regulation relating to clinical quality registries

Final report

MinterEllison has prepared this report on behalf of the Australian Commission on Safety and Quality in Health Care.

Published by the Australian Commission on Safety and Quality in Health Care
Level 5, 255 Elizabeth Street, Sydney NSW 2000

Phone: (02) 9126 3600
Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au

ISBN: 978-1-922563-03-3

The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

MinterEllison. Legislation and regulation relating to clinical quality registries, Sydney: ACSQHC; 2020

Disclaimer

The content of this document is published in good faith by the Commission for information purposes. The document is not intended to provide guidance on particular healthcare choices. You should contact your health care provider for information or advice on particular healthcare choices.

This document includes the views or recommendations of its authors and third parties. Publication of this document by the Commission does not necessarily reflect the views of the Commission, or indicate a commitment to a particular course of action. The Commission does not accept any legal liability for any injury, loss or damage incurred by the use of, or reliance on, this document.

Preface

In 2014, the Australian Commission on Safety and Quality in Health Care (the Commission) released the Framework for Australian clinical quality registries (the Framework) following endorsement by all Health Ministers. The Framework outlines guiding principles that clinical quality registries should meet in order to achieve best practice operations. In November 2019, the Commission convened the Clinical Quality Registry Advisory Group to review and update the Framework to strengthen guidance on CQR governance arrangements to better support quality improvement, outlier management, data ownership, data management and security.

As part of the revision of the Framework the Commission sought advice on Commonwealth and state & territory privacy laws and relevant legislation that may affect the operation of CQRs including how health data are stored, managed and shared for reporting on clinical outcomes via mechanisms including, but not limited to, CQRs.

MinterEllison conducted the research on Commonwealth, state & territory legislation and regulation considerations for CQR custodians, at the request of the Commission, and prepared the report *Legislation and regulation relating to clinical quality registries.*

The Commission acknowledges the work undertaken to develop the report and thanks MinterEllison for the review.

This report will inform the refinement of guidance on governance arrangements and the development of the CQR reporting policy within the Framework. It will also assist the Commission in providing guidance on the impact of legislation and regulation in relation to the roles and functions of data custodians; how health data is stored and shared; in what formats health data should be stored and the length of time data collected for the purpose of research should be held for.

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

May 2020

Legislation and regulation relating to clinical quality registries

Australian Commission on Safety and Quality in Health Care

Contents

Executive summary

In 2014, the Australian Commission on Safety and Quality in Health Care (Commission) published its Framework for Australian clinical quality registries (the Framework).

Clinical quality registries (CQRs) systematically monitor the quality (appropriateness and effectiveness) of health care within specific clinical domains by routinely collecting, analysing and reporting health-related information. CQRs are a specific type of clinical registry. They use the data they collect to identify benchmarks and variation in clinical outcomes. They then feed this information back to clinicians to inform clinical practice and decision making.[1]

There is no single organisation holding, or repository of, CQR data in Australia. In order to identify existing CQR throughout each Australian jurisdiction and the corresponding limitations on collecting, using and disclosing data held in those repositories, a review of applicable Commonwealth, State and Territory legislation and regulation.

This Report provides the legislation relating to how health data may be used, held and managed for activities relating to quality improvement in Australia. A summary of our findings is contained in Table One.

[1] Australian Commission on Safety and Quality in Health Care, Framework for Australian clinical quality registries. Sydney. ACSQHC, March 2014.

Introduction

Clinical quality registries (CQRs) systematically monitor the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information. Clinical quality registries are a specific type of clinical registry. They use the data they collect to identify benchmarks and variation in clinical outcomes. They then feed this information back to clinicians, consumers, health administrators and others to inform clinical practice and health service provision decision making. The feedback mechanism is a defining feature of clinical quality registries.

In 2014, the Australian Commission on Safety and Quality in Health Care (the Commission) released the Framework for Australian clinical quality registries (the Framework) following endorsement by all Health Ministers. The Framework outlines guiding principles that clinical quality registries should meet in order to achieve best practice operations. Specifically, the Framework:

- Recommends national operating practices
- Specifies national health information arrangements for clinical quality registries
- Provides a national infrastructure model for the efficient design, build, development, operation and security of clinical quality registries under national arrangements
- Details principles, guidelines and standards for best-practice design, build, development, operation and security of clinical quality registries under national arrangements, and
- Identifies a set of prioritisation criteria for Australian clinical quality registries to support the strategic principles for a national approach to the development of clinical quality registries.

In November 2019, the Commission convened the Clinical Quality Registry Advisory Group to review and update the Framework to strengthen guidance on CQR governance arrangements to better support quality improvement, outlier management, data ownership, data management and security.

As part of the Framework review and update, the Commission sought advice on Commonwealth and state & territory privacy laws and relevant legislation that may affect the operation of CQRs.

MinterEllison prepared the report *Legislation and regulation relating to clinical quality registries* at the request of the Commission.

Key points

Commonwealth and jurisdictional legislation and regulation, and national policies underpin the manner in which health data are stored, managed and shared for reporting on clinical outcomes via mechanisms including but not limited to, CQRs. This report provides the findings from the research undertaken on Commonwealth, state & territory legislation and regulation considerations for CQR custodians.

The report was developed via a six-step process to:

1. Identify the clinical quality data sets or data sources published by the Department of Health (Australian Government) and state and territory health departments.

2. Determine the legislation authorising the establishment and maintenance of those data sets or sources.

3. Review of the authorising legislation to identify legislation related to healthcare (including mental health), clinical quality, medical research and privacy and data.

4. Review of the identified legislation and regulation (including guidelines, policies and procedures) related to healthcare clinical quality, medical research and privacy and data holdings to determine:
    - the role and function of the data custodian
    - who can store health information data
    - how long the health information can be stored
    - if the health information can be transferred to another location for additional storage duration
    - the formats used to store health information
    - how long researchers must store the data once a study is closed.

5. Summarise the privacy legislation and regulatory considerations for CQR custodians in each Australian jurisdiction (Review tables).

6. Categorise the CQRs and data repositories identified into four types of CQRs:
    - notifiable disease registers
    - notifiable processes / events registers
    - research / record keeping registers
    - internal registers in a table.

The report provides the privacy legislation and regulatory considerations for CQR custodians in each Australian jurisdiction as presented in the Review Tables.

The report finds that:

(a) There are specific obligations relating to the collection, use and disclosure of particular data repositories

(b) There are secondary privacy obligations that apply in the collection and handling of data held by CQR custodians

(c) CQR custodians must adhere to both the specific and general obligations that apply to their use, management and disclosure of health information including in provision of information to third parties.

Conclusion

The report will inform the refinement of guidance on governance arrangements and the development of the CQR reporting policy within the Framework. It will also assist the Commission in providing guidance on the impact of legislation and regulation in relation to the roles and functions of data custodians; how health data is stored and shared; in what formats health data should be stored and the length of time data collected for the purpose of research should be held for.

Methodology

By way of summary, we have undertaken our review utilising the below methodology for each jurisdiction (noting that each jurisdiction had particular nuances):

(a) The relevant Department of Health (and equivalent Departments') websites were reviewed to identify whether the Department publishes a list of clinical quality data sets or data sources;

(b) Where lists of data sets or sources were published, the legislation authorising the establishment and maintenance of those data sets was determined and included in the relevant table;

(c) Registers of legislation for each jurisdiction were then reviewed to identify legislation related to healthcare (including mental health), clinical quality, medical research and privacy and data;

(d) Legislation and corresponding regulation were then systematically reviewed to determine:

  (i.) the nature of information authorised to be collected under the relevant legislation;

  (ii.) the custodian of information collected;

  (iii.) the time periods for which information collected under the legislation can be stored; and

  (iv.) how information collected under the legislation is required to be stored.

(e) Where relevant to legislation and regulation identified, guidelines, policies and procedures were also interrogated.

(f) This information is summarised in detail in the legislative review tables (Tables Two to Ten) (Review Tables); and

(g) The CQRs and data repositories identified in the Review Tables were categorised in Table One, into four types of CQRs: notifiable disease registers, notifiable processes / events registers, research / record keeping registers and internal registers.

Review tables

(a) The Review Tables report on privacy legislation and regulatory considerations for CQR custodians in each Australian jurisdiction.

(b) The Review Tables evidence that there are specific obligations relating to the collection, use and disclosure of particular data repositories. There will also be secondary privacy obligations that apply in the collection and handling of data held by CQR custodians. CQR custodians must adhere to both the specific and general obligations that apply to their use, management and disclosure of health information including in provision of information to third parties.

(c) For completeness, we have included information related to the declaration of the current COVID-19 pandemic and the resultant emergency powers in each jurisdiction. These emergency powers include powers to collect and act on health information relevant to the transmission of COVID-19. Interestingly, a National COVID-19 Clinical Evidence Taskforce was announced on 4 April 2020. The Taskforce will analyse emerging national and international research and data on COVID-19 to provide up-to-date information about the disease as the pandemic continues to evolve.

Findings

(a) We have categorised our findings in the Review tables into four types of CQRs – notifiable diseases, notifiable processes/events, research/record keeping and internal registers.

(b) Table One lists the CQRs identified in the Review Tables and maps these against the categories described below. It also identifies CQRs which are subject to specific restrictions on custodians disclosing data held to third parties. We note that where there are no specific legislative provisions imposed on CQR data custodians, the CQR remains subject to the overarching principles set out in the Australia Privacy Principles as contained in the *Privacy Act 1988* (Cth) and any state based equivalent privacy principles and legislation.

	Type of data repository	Description
A.	Notifiable diseases	These registers record incidence of particular diseases, for example Cancer registers.
B.	Notifiable processes / events	These registers record particular events or procedures, such as the immunisation of children, pap smears or making of orders in relation to a person's mental health.
C.	Research / record keeping	These registers include data repositories established as part of an approved Quality Assurance Activity or research study.
D.	Internal registers	These registers are maintained by organisations (for example, private health facilities) for internal purposes (eg: internal patient records, operating theatre and procedure register, and vaccination records), including clinical quality and continuous improvement (eg: root cause analysis)

Table One: CQRs maintained in Australia

Legend

Rows

A Notifiable diseases

B Notifiable processes / events

C Research / record keeping

D Internal registers

Colour code

RED: These CQRs are subject to specific provisions in relation to the use and disclosure of health information, in addition to the overarching obligations of the Australian Privacy Principles and other state based privacy laws and regulations.

BLUE: The legislation governing these CQRs does not includes specific provisions in relation to the use and disclosure of health information and is subject to the overarching obligations of the Australian Privacy Principles and other state based privacy laws and regulations.

	2 CTH	3 QLD	4 NSW	5 VIC	6 ACT	7 TAS	8 SA	9 NT	10 WA
A	***National Cancer Screening Register Act 2016***	***Public Health Act 2005*** a) Notifiable Conditions Register; b) Cancer Register, c) Notifiable dust lung disease register	***Public Health Act 2010*** a) Registers of Category 1, 2 and 3 conditions b) Public Health Registers; c) Disease Registers	***Public Health and Wellbeing Act 2008*** a) notifiable conditions register	***Public Health Act 1997*** a) notifiable conditions register b) cancer register see also *Reporting of Notifiable Conditions Code of Practice 2017*	***Public Health Act 1997*** a) Cervical screening register b) *Guidelines for Notifying Diseases and Food Contaminants* c) Tasmanian cancer registry d) notifiable contaminants registry	***Public Health Act 2011*** a) notifiable conditions register	***Public and Environmental Health Act 2011*** a) register of *Chief* Health Officer health information b) cervical screening register	***Public Health Act 2016*** a) notifiable conditions register
				Improving Cancer Outcomes Act 2014 a) Cancer register			***Health Care Regulations 2008*** a) Cancers register	***Cancer (Registration) Act 2009***	***Health Regulations*** a) Rheumatic Heart Disease

	2 CTH	3 QLD	4 NSW	5 VIC	6 ACT	7 TAS	8 SA	9 NT	10 WA
							South Australian Public Health (Cervical and Related Cancer Screening) Regulations 2012 ***Health Care Regulations 2008*** a) birth register b) cancer register	a) register of cancer diagnoses	a) Register of Western Australia b) Health (Western Australian Cancer Register c) Cervical Screening Register) d) Western Australian Register of Developmental Anomalies e) Stimulant Induced Psychosis Register f) Lead Poisoning Register
B	***Australian Immunisation Register Act 2015*** ***Research Involving Human Embryos Act 2002***	***Public Health Act 2005*** a) environmental health event register b) collection of maternal death statistics c) pap smear register d) perinatal statistics collection e) research register	***Poisons and Therapeutic Goods Regulation 2008*** a) pharmacy transaction register	***Mental Health Act 2014*** a) Young persons receiving electroconvulsive treatment reports b) persons receiving electroconvulsive, neurosurgical or restrictive treatment reports ***Public Health and Wellbeing Act 2008*** a) young persons receiving electroconvulsive treatment reports	***Public Health Act 1997*** a) registers of public health indicators including morbidity and mortality ***Medicines, Poisons and Therapeutic Goods Act 2008*** a) monitored medicines database	***Mental Health Act 2013*** a) long-term voluntary patient records	***Health Care Regulations 2008*** a) birth register ***Assisted Reproductive Treatment Act 1988*** a) donor conception register	***Public and Environmental Health Act 2011;*** a) register of perinatal information	***Health (Miscellaneous Provisions) Act 1911*** a) Anaesthetic Mortality Committee, b) Maternal Mortality Committee; c) Perinatal and Infant Mortality records

	2 CTH	3 QLD	4 NSW	5 VIC	6 ACT	7 TAS	8 SA	9 NT	10 WA
	This register does not include health information and lists information relating to licensed providers of assisted reproductive technology.	***Mental Health Act 2016*** a) advance health directives; b) enduring powers of attorney for a personal matter; and c) appointments of nominated support persons.		***Health Services Act 1988*** a) infections and infection control reports b) electroconvulsive treatment reports c) emergency admissions reports d) safety or sentinel event reports	***Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2019 (No 1):*** Australian Immunisation Register; National		***Public Health Act 2011*** a) immunisation register		***Medicines and Poisons Act 2014* (WA)** a) information relating to the supply of drugs of addiction and drug dependent and oversupplies
		Health (Drugs and Poisons) Regulation 1996 a) controlled drugs record			***Mental Health Act 2015:*** a) affected person's register; b) restraint register				***Human Reproductive Technology Act 1991*** a) records of participants in reproductive technologies
C	***Health Insurance Act 1973:* Quality Assurance Activities**	***Hospital and Health Boards Act 2011*: Quality Assurance Activities**	***Health Administration Act 1982*;** ***Health Administration Regulation 2015***	***Health Services Act 1988*** a) Health purchasing data	***Medicines, Poisons and Therapeutic Goods Act 2008*** a) monitored medicines database	***Quality and Safety Framework for Tasmania's DHHS Funded Community Sector*** a) monitoring of continuous improvement activities	***Health Care Act 2008*** a) quality improvement or authorised research activities	***Health Services Act 2014*** a) monitoring of performance, funding and compliance	***Health Services (Quality Improvement) Act 1994*** a) quality improvement committees b) the Maternal Mortality Committee c) Perinatal and Infant Mortality Committee d) Anaesthetic Mortality Committee
	National Statement on Ethical Conduct in Research Involving Humans		**Assisted Reproductive Technology Act 2007** a) ART registers	***Public Health and Wellbeing Act 2008*** a) The Consultative Council on Obstetric and Paediatric Mortality	***Health Act 1993*** a) Quality Assurance Committees				

	2 CTH	3 QLD	4 NSW	5 VIC	6 ACT	7 TAS	8 SA	9 NT	10 WA
	Epidemiological Studies (Confidentiality) Act 1981 ***My Health Records Act 2012***			and Morbidity (CCOPMM)	***ACT Health Care Facilities Code of Practice 2001*** a) internal patient records				***Human Reproductive Technology Act 1991*** a) research register
D		***Private Health Facilities Act 1999*** a) admission and discharge register; b) birth register; c) operating theatre and procedure register; and d) mental health register	***Private Health Facilities Act 2007*** a) birth register b) procedure register c) register of patients d) root cause analyses	***Health Services Act 1988*** a) internal patient records b) pre-admission clinical risk and clinical records c) patient admission and discharge register d) staff register; operation theatre register e) birth register; f) quality and safety data register	***Medicines, Poisons and Therapeutic Goods Act 2008*** a) controlled medicines register b) dangerous poisons register a) prohibited substances register **Vaccinations by Pharmacists Direction 2019 (No 1)** c) vaccination records	***Mental Health Act 2013*** a) forensic patient records	***Health Care Regulations 2008*** a) internal patient records	***Medicines, Poisons and Therapeutic Goods Act 2012*** a) registers of prescribed substance	***Human Reproductive Technology Act 1991*** a) records of reproductive technologies and products ***Health Services Act 2016*** systems containing performance data ***Medicines and Poisons Regulations 2016*** a) records of restricted medicines

Table Two: Commonwealth

Table Two summarises Commonwealth legislation which is relevant to the collection and storage of health information. Some, but not all of the legislation summarised in Table Two is relevant to establishing a national CQR as a quality assurance activity or as a pilot within a research framework:

CQR as a quality assurance activity

An individual or organisation who wishes to seek a declaration in relation to a quality assurance activity (**QAA**) under the Commonwealth legislation (*Health Insurance Act 1973*) must do so by completing the application form approved by the Australian Government Department of Health, or delegate of the Minister. The application form can be downloaded from the Applying for a declaration under the Commonwealth Qualified Privilege Scheme page.

If the applicant is engaged in Commonwealth funded activities (e.g. a Medicare approved provider or public hospital) the approved QAA will fall within the Commonwealth qualified privilege scheme. The qualified privilege scheme provides safeguards for health care professionals who engage in declared QAAs by prohibiting the release of certain identifiable information relating to that activity and by protecting certain persons who engage in those activities from civil liability. The Commonwealth qualified privilege scheme is designed to complement, not override any State schemes.

Where a QAA is a declared QAA and subject to the qualified privilege scheme, information obtained in the course of the QAA and the identify of those involved may not be able to be disclosed, even for the purposes of a CQR. These restrictions should be carefully assessed on a case-by-case basis.

When making a decision to declare an activity as a QAA, the Minister, or delegate of the Minister, must be satisfied it is in the public interest to declare the activity on the grounds that the activity will:

- encourage participation in the activity, or in the case of an activity having previously been undertaken
- encourage participation to a greater extent than in the previous activity; and
- encourage acceptance, implementation and monitoring of any recommendations which arise from the activity.

The Minister, or the delegate of the Minister may also take into account whether the activity has, or should have, ethics committee approval. The Parliament has the power to request additional information or disallow a declaration. If this occurs a declaration would cease to have effect.

CQRs within a research framework

An individual or organisation who wishes to establish a CQR as a pilot and/or for development as a national CQR within a research framework requires an identifiable custodian to operate the CQR with approval by a human research ethics committee and acknowledgment by the contributing institutions of their responsibilities as provided in the National Statement. Some HRECs are able to approve national research project, however this may vary and should be confirmed for each new CQR that is established. This may require local site specific assessment review by the authorising institution.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
Commonwealth							
1.	***Australian Immunisation Register Act 2015*** ***Australian Immunisation Register Rule 2015***	The Commonwealth is responsible for establishing and keeping the **Australian Immunisation Register**. (s 8)	A person may collect, make a record of, disclose, or otherwise use health information for the purpose of including it on the Australian Immunisation Register. (s 22(1)) Commonwealth authorities, State and Territory health authorities, contracted service providers, primary health network operators, and recognised vaccination providers may make a record of, disclose or otherwise use information obtained through in their role in relation to the Australian Immunisation Register for limited purposes.	How long identified information can be stored is not specified.[2]	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

[2] The Australian Privacy Principles (see Row 11) require that when personal information is no longer required for the purpose for which is was used, it must be destroyed or de-identified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			(s 22(2), rs 5,6,7, and 8) The Commonwealth must not disclose health information data where requested not to by the person to whom the data relates. (s 11)				
2.	***Australian National Preventive Health Agency Act 2010*** **CEO** means the Chief Executive Officer of the Australian National Preventive Health Agency	The Australian National Preventive Health Agency is responsible for supporting its CEO in collecting, analysing, interpreting and disseminating information relating to preventative health. (ss 8 and 11)	The CEO of the agency may make arrangements with State or Territory governments for governmental officers to perform services in connection with the CEO's functions, including in collecting, analysing, interpreting and disseminating information relating to preventative health. (s 26) The CEO may engage consultants on the same basis. (s 27) This may require these officers to store health information.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
3.	***Health Insurance Act 1973*** This Act contains obligations for health service providers engaged in quality assurance activities.[3]	The Minister of Health may declare a quality assurance activity described in the declaration to be a quality assurance activity for the purposes of the Act. (s 124X)	Health service providers are prohibited from disclosing information that became known solely as a result of those activities. (s 124Y)	Quality assurance activities remain subject to the non-disclosure obligations of the Act for 5 years. (s 124X)	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.
4.	***Healthcare Identifiers Act 2010*** ***Healthcare Identifiers Regulations 2010***	Healthcare providers, and the Chief Executives of Medicare, Veterans' Department and Defence Department are responsible for collecting, using or disclosing identified health information for a number of purposes including the provision of healthcare, aged care purposes, maintenance of adequate records, and the conduct of approved research. (ss 12, 13, 14, and 16) The Chief Executive of Medicare is	Healthcare providers may disclose health information to employees and contracted service providers for the purpose of them carrying out their duties to the healthcare provider. (s 36A) Healthcare providers may disclose healthcare identifiers for the purpose of: a) providing healthcare; or b) managing, funding monitoring or evaluating	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Entities must store health information in a way that protects any healthcare identifiers from misuse, loss, and unauthorised access, modification or disclosure. (s 27)	How long researchers must store data once a study is closed is not specified.

[3] Declarations of Quality Assurance Activities made under the *HIA* are listed in **Annexure A**.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		responsible for collecting, using and disclosing health information for the purposes of the My Health Record system. (s 15; reg 8)	healthcare. (reg 9)				
5.	**National Statement on Ethical Conduct in Research Involving Humans** The National Statement is intended for use by: • any researcher conducting research with human participants; • any member of an ethical review body reviewing that research; • those involved in research governance; and • potential research participants.	All data collections should have an identified custodian to enable access by researchers or participants to the data while maintaining it in a protected form. The custodian of the data may be the individual researcher or agency who collected the information, or an intermediary that manages data coming from a number of sources. (3.1.55) Institutions (not further defined) have responsibilities for the conduct of research. (5.7.3)	Any sharing of data or information between research collaborators and research sites must be secure and proportional to the risks associated with, and the ethical sensitivity of the information. (3.1.58) Where the potential disclosure of findings or results to third parties can be anticipated, researchers should identify: a) whether, to whom and under what circumstances the findings or results will be disclosed; b) whether potential participants will be forewarned that there may be such a disclosure;	The National Statement on Ethical Conduct in Research Involving Humans does not specify how long identified health information can be stored.	The custodian of the data may be an intermediary that manages data coming from a number of sources. (3.1.55)	Researchers should adopt methods to reduce the risk of identification during collection, analysis and storage of data and information. (3.1.41) When multiple researchers are collaborating on collection, storage and/or analysis of data or information, they should agree to the arrangements for custodianship, storage, retention and destruction of those materials, as well as to rights of access, rights to analyse/ use and re-use the data or information and the right to produce research outputs	Where applicable, records should be preserved for long enough to enable participants to be traced in the event that evidence emerges of late or long-term health-related effects. (3.1.48) Data, information and biospecimens used in research should be disposed of in a manner that is safe and secure. (3.1.49) Data and information of cultural, historical or other significance such that they should be retained beyond the minimum retention period should not be disposed of. (3.1.74)

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			c) the risks associated with such a disclosure and how they will be managed; and d) the rationale for communicating and/or withholding the findings or results and the benefits and/or risks to participants of disclosure/ non-disclosure. (3.1.66) In circumstances where the imperative to disclose findings or results emerges after the research has commenced, researchers must develop a strategy for addressing this and promptly advise and seek advice from reviewers. (3.1.68)			based upon them. (3.1.44) Researchers should develop a data management plan, proportional to the risks of the research project and the sensitivity of the information, that addresses their intentions elated to generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information, the risks associated with these activities and any strategies for minimising those risks. (3.1.45, 3.1.46, and 3.1.56) Shared or banked data or information that is stored in a form that can identify individuals can sometimes be used in research that qualifies as negligible or low risk research; however, it cannot be used in research that	

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
						is exempt from ethics review. (3.1.62, and 5.1.22) If inclusion of information in databases is a necessary component of the research or if information is to be shared for other research, efforts should be made to minimise the potential for re-identification. (3.3.21)	
6.	***National Cancer Screening Register Act 2016*** ***National Cancer Screening Register Rules***	The individual healthcare provider prescribed by the rules for a type of screening test or diagnosis prescribed by the rules must notify the Commonwealth Chief Medical Officer. (s 13)	The register may include information relating to individuals in connection with screening associated with bowel cancer. (s 10)	Authorised dealing with information stored on the register are set out in s 17 of the Act.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The register may include the details about the individual, the individual's healthcare provider, screening tests undergone or to be undergone by the individual, and the diagnosis. (s 10)	How long researchers must store data once a study is closed is not specified.
7.	***Epidemiological Studies (Confidentiality) Act 1981*** The Act relates to epidemiological studies conducted by and on behalf of the	Who is responsible for health information data is not specified.	A person who has assisted, or is assisting, in the conduct of a prescribed study may only disclose health information acquired by reason of their	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	Commonwealth Government.		involvement in that study in limited circumstances. (ss 4,5,6, 7, and 9) Health information concerning an individual may be given to a third party with the individual's consent. (s 7) De-identified conclusions based on, statistics derived from, or particulars of procedures used in a prescribed epidemiological study may be published. (s 11)				
8.	***Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research 2018***[4]	Who is responsible for health information data is not specified.	Special care should be taken when disclosing research concerning Aboriginal and Torres Strait Islander peoples. (2.5, see also *NHMRC Ethical Guidelines for Research with Aboriginal and Torres*	The period for which data should be retained should be determined by prevailing standards for the specific type of research and any applicable state, territory or national legislation. The	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Researchers should comply with their institution's data management plans regarding the form in which information will be stored (3). Researches should adhere to national and international standards	The period for which data should be retained should be determined by prevailing standards for the specific type of research and any applicable state, territory or national legislation. The

[4]Adherence to the 2018 Code is a prerequisite for the receipt of funding by the National Health and Medical Research Council. In this sense, compliance is not mandatory.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			Strait Islander Peoples)	guideline provides the following guidance: a) In general, the minimum period for retention of research data is 5 years from the date of publication. b) For most clinical trials, retaining data for 15 years or more may be necessary. c) For gene therapy, health information must be retained permanently. d) For work with community, cultural or historical value, health information should be retained permanently. (2.3)		for data description including: a) using Digital Object Identifiers for datasets; and b) ORCID IDs for researchers.(3.1)	guideline provides the following guidance: a) In general, the minimum period for retention of research data is 5 years from the date of publication. b) For most clinical trials, retaining data for 15 years or more may be necessary. c) For gene therapy, health information must be retained permanently. d) For work with community, cultural or historical value, health information should be retained permanently. (2.3)
9.	***Research Involving Human Embryos Act 2002***	The NHMRC Licensing Committee maintains a database containing information in relation to each licence regulating the use of excess ART	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The License Database must be publicly available. (s 29) The License Database may be kept in electronic form. (s 29)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		embryos, other embryos and human eggs. This does not contain identified health information of participants. (s 29)					
10.	**NHMRC Guidelines** under sections 95 and 95A of the *Privacy Act 1988* The NHMRC Guidelines apply to agencies and researchers engaged in health care and medical research. They are not legally binding documents themselves, but may be incorporated into research funding agreements. **Organisation** means: a) an individual; or b) a body corporate; or c) a partnership; or d) any other unincorporated association; or e) a trust; that is not a small business operator, a	Organisations who collect, use or disclose health information must immediately report anything that might warrant review of ethical approval to the Human Research Ethics Committee. (A.2.8, A.3.9, B.2.8, B.3.9, C.2.8, and C.3.9, *s 95A Guidelines;* 2.7 *s 95 Guidelines*) The NHMRC must annually report to the Commissioner all details recorded under the guidelines of research, compilation or analysis of statistics, or health service management activities conducted under the guidelines. (F.1, *s 95A Guidelines;* 5.1 *s 95 Guidelines)*	Organisations may collect, use, or disclose health information for the purposes of: a) medical research; b) research relevant to public health or public safety; c) statistical compilation or analysis relevant to public health or public safety; or d) management funding or monitoring of a health service e) where necessary to achieve that purpose, and approved by a Human Research Ethics Committee. (A.1, B.1, and C.1, s 95A Guidelines; 1, s 95 Guidelines)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	registered political party, an agency, a State or Territory authority or a prescribed instrumentality of a State or Territory.						
11.	***My Health Records Act 2012*** ***My Health Records Regulation 2012*** ***My Health Records Rule 2016***	The Chief Executive of Medicare is the registered repository operator of the My Health Record system. (s 38) The Australian Digital Health Agency and the Chief Executive of Medicare are responsible for collecting, using and disclosing health information for the purposes of: a) maintaining the My Health Record system (s 58A; see also Sch 1, s 7; s 58); b) verifying representation; and c) verifying the identify of healthcare	The Australian Digital Health Agency may register third parties as repository operators, portal operators, or contracted service providers who may hold health information as part of performing their duties. (Part 3, Division 3, *Act*; r 37) My Health Record Participants may collect, use and disclose health information where the relevant healthcare recipient would reasonably expect it, or in response to a request by the Secretary. (s 63) The Australian Digital Health Agency, registered repository operators, registered	The Australian Digital Health Agency must ensure that records containing health information is retained for the period: a) beginning when the record is first uploaded to the National Repositories Service; and b) ending the earliest of 30 years after the death of the healthcare recipient, 130 years after the birth of the healthcare recipient, and when the record is required to be destroyed because the healthcare	The Australian Digital Health Agency , registered repository operators, registered portal operators, and a registered contracted service providers must not transfer, hold, or process health information outside Australia. (s 77)	The Australian Digital Health Agency must establish and maintain default access controls and advances access controls that permit access to and limited editing of health information, as well as allow healthcare recipients to block access to nominated entities. (r 5) Only shared health summaries, advanced care planning information and records has been prepared by registered individual healthcare providers may be uploaded to My Health Record. (s 45(b)(ii); r 19) Healthcare providers organisation may only upload advance care	The Australian Digital Health Agency must ensure that records containing health information is retained for the period: a) beginning when the record is first uploaded to the National Repositories Service; and b) ending the earliest of 30 years after the death of the healthcare recipient, 130 years after the birth of the healthcare recipient, and when the record is required to be destroyed because the healthcare

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		recipients. (s 58A; Sch 1, s 8) The Veterans' Affairs Department and Defence Department are responsible for collecting, using and disclosing health information for the purposes of: a) maintaining the My Health Record system; and b) verifying the identify of healthcare recipients. (s 58A; Sch 1, s 8). Repository and portal operators are responsible for collecting, using and disclosing health information for the purpose of maintaining the My Health Record system. (s 58A; Sch 1, s 8) The Attorney-General's Department are responsible for collecting, using and disclosing health information for the	portal operators, and a registered contracted service providers must not transfer, hold, or process health information outside Australia. (s 77)	recipient's registration is cancelled. (s 17) When the Australian Digital Health Agency is required to cancel the registration of a healthcare recipient, the Australian Digital Health Agency must destroy all health information other than: a) the name and healthcare identifier of the recipient; b) the name and identifier of the person who requested the cancellation, where applicable; and c) the day the cancellation decision takes effect. (s 17)		planning information with the healthcare recipient's consent. (r 32A) Healthcare providers, contracted service providers and operators must ensure that information technology systems used to access the My Health Record system: a) restrict access to unauthorised persons; and b) provide security around identifying information. (rs 44 and 49) Healthcare providers, contracted service providers and operators must maintain and comply with a written information security policy. (r 47)	recipient's registration is cancelled. (s 17)

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		purpose of verifying the identify of healthcare recipients. (s 58A*;* Sch 1, s 8; reg 4.1.1) The Data Governance Board are responsible for assessing applications for collection, use or disclosure of de-identified health information for research or public health purposes (s 83). The Data Governance Board may delegate its functions to third parties in limited circumstances. (s 96G)					
12.	***Privacy Act 1988*** ***Australian Privacy Principles* (APPs)** under ss 14 and 15 of the *Privacy Act.* ***Privacy (Australian Government Agencies – Governance) APP Code 2017***	Organisations are responsible for collecting, using and disclosing health information where necessary for the purposes of: a) research relevant to public health or safety; b) statistical compilation or	Organisations can collect, use or disclose health information where necessary for the purposes of: a) research relevant to public health or safety; b) statistical compilation or analysis relevant	Organisations must take reasonable steps to destroy or de-identify health information once it is no longer needed for any official purpose, except where contained in a Commonwealth record or otherwise	Organisations must take reasonable steps to destroy or de-identify health information once it is no longer needed for any official purpose, except where contained in a Commonwealth record or otherwise	Organisations may only adopt government related identifiers of individuals in limited circumstances *(*APP 9*).* Organisations must take reasonable steps to protect health information from misuse, interference, loss, and unauthorised	Organisations must take reasonable steps to destroy or de-identify health information once it is no longer needed for any official purpose, except where contained in a Commonwealth record or otherwise

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	under Division 2 of the *Privacy Act.* The Act applies to and Commonwealth agencies and 'organisations', which includes individuals, bodies corporate, partnerships, unincorporated associations and trusts.	analysis relevant to public health or public safety; or c) the management, funding or monitoring of a health service. (ss 16B(2) and 16B(3); APP 3.4 and 3.4) An organisation may be required to de-identify health information before disclosure. (s 6.4*)* Organisations must maintain and comply with a privacy policy that governs how they deal with personal and health information. (APPs 1.3 and 1.4) Australian government agencies must have a designated privacy officer who has primary responsibility for matters of data management for the agency. (s 10, Code)	to public health or public safety; or c) the management, funding or monitoring of a health service. (ss 16B(2) and 16B(3)) Organisations can disclose health information to overseas recipients in limited circumstances including where: a) the organisation takes reasonable steps to ensure the recipient does not breach the Australian Privacy Principles; or b) the organisation reasonably believes the recipient is subject to a law that has a substantially similar effect to the APPs. (APP 8).	protected by law. (APP 11.2)[5]	protected by law. (APP 11.2)	access, modification or disclosure. (APP 11.1)	protected by law. (APP 11.2)

[5] Organisations are also subject to the requirements in each state and territory under public records legislation.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
13.	***Privacy Market and Social Research Code 2014*** This code applies to all full and associate members of the Association of Market and Social Research Organisations who are an organisation covered by the *Privacy Act*.	Market and Social Research organisations are responsible for maintaining and complying with a research information privacy policy. (ss 1.3 and 1.4)	Market and Social Research organisations may only collect health information where reasonably necessary and with consent, or where otherwise required by law. (s 3.3) Organisations can disclose health information to overseas recipients in limited circumstances including where: a) the organisation takes reasonable steps to ensure the recipient does not breach the Australian Privacy Principles; or b) the organisation reasonably believes the recipient is subject to a law that has a substantially similar effect to the Australian Privacy Principles. (s 8)	Market and Social Research organisations must retain identifiable health information only for as long as necessary to achieve research purposes. Once research purposes have been achieved, research organisations must destroy or de-identify all health information and any copies. (s 11.3) Market and Social Research organisations must accept and act on requests for identifiable research information to be destroyed or de-identified except in limited circumstances. (s 13.6)	Market and Social Research organisations must retain identifiable health information only for as long as necessary to achieve research purposes. Once research purposes have been achieved, research organisations must destroy or de-identify all health information and any copies. (s 11.3)	Where it is necessary for Market and Social Research organisations to retain identifiable research information, identifying details must, as far as practicable, be stored separately from other information, with security measures in place to prevent the identification of individuals. (s 11.5) Market and Social Research organisations may only adopt government related identifiers of individuals in limited circumstances. (s 9) Organisations must take reasonable steps to protect health information from misuse, interference, loss, and unauthorised access, modification or disclosure. (s 11.1)	Market and Social Research organisations must retain identifiable health information only for as long as necessary to achieve research purposes. Once research purposes have been achieved, research organisations must destroy or de-identify all health information and any copies. (s 11.3)

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			Organisations may have to de-identify health information. (ss 6.2B, 6.4 and 6.5)				

Table Three: Queensland

Table Three summarises Queensland legislation which is relevant to the collection and storage of health information. Some, but not all of the legislation summarised in Table Three is relevant to establishing a national CQR as a quality assurance activity or as a pilot within a research framework. QAAs are subject to special protections that do not otherwise apply to all research conducted for the purposes of maintaining quality and safety or continuous improvements in the health care sector.

CQRs as a Quality assurance activity

In Queensland, protected QAAs are established pursuant to Part 6 of the *Health and Hospital Boards Act 2011* (**HHBA**). QAAs may be established by public and private health services, professional associations, societies or colleges or the Department of Health Chief Executive. Entities are required to notify the Chief Executive that a QAA committee has been formed.

Entities that are covered by the *HHBA* may also be eligible to apply for a declaration under the *Health Insurance Act 1973* if they provide Commonwealth funded services, however the Commonwealth qualified privilege scheme offers similar protections to the *HHBA* so this additional step may not be necessary.

CQRs within a research framework

An individual or organisation who wishes to establish a CQR as a pilot and/or for development as a national CQR within a research framework requires an identifiable custodian to operate the CQR with approval by a human research ethics committee and acknowledgment by the contributing institutions of their responsibilities as provided in the National Statement. This may require local site specific assessment review by the authorising institution.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
Queensland							
1.	***Public Health Act 2005*** ***Public Health Regulation 2018*** **Chief Executive** means the Chief Executive of the Department of Health	The Chief Executive is responsible for the **environmental health event register.** (s 48(1))	The Chief Executive may store the relevant health information data, including in electronic form. (s 48(2))	The Public Health Act does not specify the duration for which the data may be stored. Public sector authorities that create and manage clinical records are covered by the *Health Sector (Clinical Records) Retention and Disposal Schedule* and *Public Records Act 2002 (Qld)*. Accordingly, public records must generally be kept for a minimum of 10 years, depending on the type of record.[6]	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Chief Executive may keep the register in a form the Chief Executive considers appropriate, including an electronic form. (s 48(2))	How long researchers must store data once a study is closed is not specified. [7]
		The Chief Executive is responsible for establishing and keeping a **Notifiable Conditions Register.** (s 67)	The Chief Executive is responsible for storing a register of the persons for whom notifiable conditions have been reported. (s 67(1))	How long identified information can be	Whether identified health information can be transferred to another location for additional storage	A person required to notify the Chief Executive may do so using an anonymity code. (s 74) (not defined and not used	How long researchers must store data once a study is closed is not specified.

[6] This is the position for all public sector authorities in Queensland.

[7] Research studies funded by the National Health and Medical Research Council must maintain records in accordance with the National Statement – requirement for human research and relevant Records Authority issued by the National Archives of Australia (Archives Act 1983).

Legislation		Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Doctors, persons in charge of hospitals, and directors of pathology laboratories must are responsible for notifying the Chief Executive of notifiable conditions.		stored is not specified.[8]	duration is not specified.	elsewhere in the *Public Health Act*)	
		The Chief Executive is responsible for collecting and keeping a **collection of maternal death statistics.** (ss 228D and 228G)	The Chief Executive may store health information data comprising the collection of maternal death statistics. (ss 228D and 228G) A health professional who has had primary responsibility for the care or treatment of a woman while she was pregnant or within 365 days after the end of her pregnancy must notify the Chief Executive of the woman's death. (s 228F)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Chief Executive may keep the collection in a form the Chief Executive considers appropriate, including an electronic form. (s 228D(2))	How long researchers must store data once a study is closed is not specified.

[8] The Australian Privacy Principles (see Table One: Commonwealth) require that when personal information is no longer required for the purpose for which is was used, it must be destroyed or de-identified.

Legislation		Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		The Chief Executive is responsible for collecting information and keeping a register of persons for whom notifications about cancer have been made. (ss 230 and 236, the **Cancer Register**)	The Chief Executive may enter into a written agreement with a person prescribed under a regulation (the contractor) for the contractor to keep the register for the Chief Executive. The Chief Executive must take reasonable steps to ensure the contractor complies with the agreement. (s 232) The Chief Executive may give a written direction for notification to be given to the contractor in place of the Chief Executive. (s 235)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Chief Executive may keep the register in a form the Chief Executive considers appropriate, including an electronic form. (s 230(3))	How long researchers must store data once a study is closed is not specified.
		The Chief Executive is responsible for collecting information and keeping a **pap smear register** to record identifying and clinical information about women. (ss 253 and 265)	Unless the woman elects for her information not to be included on the register, a director of a pathology laboratory must provide information to the Chief Executive. (s 259)	The Chief Executive must remove an indiv registered screening history from the register, the Chief Executive must remove the woman's history from the register, unless the woman withdraws her request before the period ends. (s 263)	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Chief Executive may keep the register in a form the Chief Executive considers appropriate, including an electronic form. (s 253(2))	How long researchers must store data once a study is closed is not specified.

Legislation		Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			In some circumstances, the Chief Executive may give health practitioners access to the registerer. (s 272) The Chief Executive is responsible for monitoring access to information. (s 276)		However, The Chief Executive may arrange for the transfer of confidential information for inclusion in the register. (s 230)	Clinical and identifying information about a woman is to be included in the register unless the woman elects for it not to be included. (s 255(1))	
		The Chief Executive is responsible for collecting information, establishing, and keeping a register of notifications about notifiable dust lung diseases given to the Chief Executive. (ss 279AB and 279AG, the **notifiable dust lung disease register**) Similarly, if a coal mine worker is diagnosed with a reportable disease, notice must be given to the Chief Inspector of the relevant coal mine for the purposes of record keeping. (s 198, *Coal Mining Safety and Health Act 1999*)	If a prescribed medical practitioner diagnoses a person as having a notifiable dust lung disease the prescribed medical practitioner must notify the Chief Executive about the notifiable dust lung disease unless the practitioner has a reasonable excuse (s 279AF) or has notified the notifiable lung disease under the *Coal Mining Safety and Health Act 1999*; or another medical practitioner, who is authorised to provide a health assessment about the person. (s 279AF)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Chief Executive may keep the register in a form the Chief Executive considers appropriate, including an electronic form. (s 279AB(3))	How long researchers must store data once a study is closed is not specified.

Legislation		Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			The Chief Executive must give the Minister of health a report stating the number of notifications given to the Chief Executive under this part during the financial year; and the types of notifiable dust lung diseases recorded in the register during the financial year; and the actions the department has taken to implement the purposes of the register; and any other information about a notifiable dust lung disease the Chief Executive considers appropriate. (s 279AJ)				
		The Chief Executive is responsible for collecting information and keeping a collection of perinatal statistics (ss 215(1) and 218, the **perinatal statistics collection**) **Designated persons** include persons in charge of hospitals, doctors, midwives, and	After a delivery, the **designated person** must notify the Chief Executive in the approved form. (s 217)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Chief Executive may keep the collection in a form the Chief Executive considers appropriate, including an electronic form. (s 215(2))	How long researchers must store data once a study is closed is not specified.

Legislation		Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		if no health practitioner is present, the mother.					
		The Chief Executive is responsible for establishing and keeping a register of granted applications for health information held by a health agency. (s 288, the **research register**) A person may apply in writing to the Chief Executive to be given health information held by a health agency for research being conducted by the person or by an entity of which the person is a member. (s 282)	The Chief Executive may grant an application for health information held by a health agency only if the Chief Executive is satisfied it is in the public interest, having regard to: a) the opportunities the research will provide for increased knowledge and improved health outcomes; and b) the privacy of individuals to whom the health information relates; and c) the identification of any person by the information is necessary for the relevant research. (s 284)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Chief Executive may keep the collection in a form the Chief Executive considers appropriate, including an electronic form. (s 215(2))	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
2.	***Declared Public Health Emergency: COVID-19*** under the *Public Health Act 2005*	The Chief Health Officer has powers to make directions to respond to the public health posed by COVID-19, including with respect to collection of health information.	The Chief Health Officer will collect and use information as and when required and permitted within the powers of the declaration and directions issued by government.	The Declaration and associated directions do not currently specify how long records or information obtained in the course of exercising the powers under the directions may be kept.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Declaration and associated directions do not specify a format for storing records or information obtained in the course of exercising the powers under the directions .	How long researchers must store data once a study is closed is not specified.
3.	***Health Transparency Act 2019*** **Chief Executive** means the Chief Executive of the Department of Health The Act applies to information about public and private sector health service facilities; and State aged care facilities and private residential aged care facilities; and quality and safety information about public and private sector health service facilities and residential care information about State aged care	The Chief Executive may collect and publish health information. (s 11)	The Chief Executive may publish information in any way that allows the information to be accessed by members of the public. (s 12) The Chief Executive may, request that an approved provider who provides residential care at a **private residential aged care facility** give the Chief Executive general information or residential care information. (s 13). The Chief Executive may require a **public sector health service or residential aged care service** to give general information, quality and safety	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Chief Executive may publish information in any way that allows the information to be accessed by members of the public. (s 12)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	facilities; and private residential aged care facilities.		information or residential care information. (s 17) The Chief Executive may require the licensee of a **private health facility** to give general information and quality and safety information. (s 18)				
4.	***Private Health Facilities Act 1999*** ***Private Health Facilities Regulation 2016***	The regulations prescribe Hardes and Associates Pty Ltd as the entity responsible for evaluating, managing, monitoring or planning health services by reviewing patterns of health services delivery and projecting the future demand for, and supply of, health services. (reg 7) None of the standard conditions for licence reporting specify who is responsible for health information data, however the chief health officer may impose additional conditions as they see fit. (s 23)	Disclosure of health information data is permitted to a wide range of parties. (s 147) None of the standard conditions for licence reporting specify who can store health information data, however the chief health officer may impose additional conditions as they see fit. (s 23)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified. Disclosure to bodies outside Queensland Health is authorised in limited circumstances, including e.g. under the *Coroners Act 2003* (Qld), which may require health information to be transferred to an additional location and stored for an additional duration. (ss 147, 147A, 147B, 147C, and 147D)	None of the standard conditions for licence reporting specify the format for storage of health information data, however the chief health officer may impose additional conditions as they see fit. (s 23)	How long researchers must store data once a study is closed is not specified, however the chief health officer may impose additional conditions as they see fit. (s 23)

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
					None of the standard conditions for licence reporting specify whether health information data may be transferred to another location for additional storage, however the chief health officer may impose additional conditions as they see fit. (s 23)		
5.	***Information Management Standard*** under the *Private Health Facilities Act 1999*	Private health facilities under the *Private Health Facilities Act 1999* (Qld) are responsible for maintaining the following internal registers: a) Admission and discharge register; b) Birth register; c) Operating theatre and procedure register; and d) Mental health register.	The *Information Management Standard* allows disclosure of health information data to a wide range of parties. Where data is lawfully disclosed, storage of the data by recipients is limited only by the requirement that they comply with Australian Standards ISO/IEC 27001:2015 and ISO/IEC 27002:2015.	A health facility must retain and store its own medical records for a minimum of: a) 10 years after the latter of the last clinical attendance or medicolegal action; b) in the case of obstetric and minors' records, 10 years after the child turns 18; or c) in the case of patients with diminished decision-making capacity, 10 years after the patient's	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Records storage security must comply with Australian Standards ISO/IEC 27001:2015 and ISO/IEC 27002:2015.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
				decision-making capacity is no longer limited, or 80 years from the patient's birth.			
6.	***Hospital and Health Boards Act 2011*** ***Queensland Health Directive*** under ss 47 and 50 of the *Act* ***Service Agreements***	QLD Health is responsible for assigning Data Custodians and Application Custodians their roles and responsibilities. (*Queensland Health Directive*) All Quality Assurance Committees must adopt and abide by a privacy policy governing the acquisition, storage, disclosure and destruction of relevant information, including health information data. (reg 23) Service Agreements between QLD Health and local Hospital and Health Services (**HHS**) require HHSs to provide data in accordance with the provisions of the Hospital and Health Boards Act, Public	The *Hospital and Health Boards Regulation 2012* (Qld)) prescribes the following parties may collect and store health information data for limited purposes: a) Alfred Health ABN 27 318 956 319; b) Monash University ABN 12 377 614 012; c) Hardes & Associates Pty Ltd ACN 079 150 940; d) the Australian Orthopaedic Association ACN 000 759 795; e) the Australasian Cardiac Surgery Research Institution ABN 44 099 817 106; f) the Department of Communities, Child Safety and Disability Services;	HHS Service Agreements do not currently specify how long health information data may be stored, but do specify that such requirements may be specified in an amended Schedule 4.	Disclosure to bodies outside Queensland Health is authorised in limited circumstances, including for approved research, which may require health information to be transferred to an additional location and stored for an additional duration. (ss 142, 142A, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 161)	Queensland Health's Information Security Directive issued under ss 47 and 50 of the *Hospital and Health Boards Act 2011* (Qld) requires all health information data be stored in line with Queensland Health Information Security Management System and international standard ISO 27001:2013 (at 6.1). The *Hospital and Health Boards Act 2011* (Qld) allows storage of data using electronic information management systems. (s 23) HHS Service Agreements do not currently specify a storage format for	How long researchers must store data once a study is closed is not specified, but such a requirement may be imposed in an amended Schedule 4.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Health Act and Private Health Facilities Act and as and when requested by the Chief Executive. (Service Agreements) Under its Service Agreements, QLD Health is responsible for producing a monthly report of activity levels and HHS performance. (Service Agreements)	g) the Department of Housing and Public Works; h) the Florey Institute of Neuroscience and Mental Health ABN 92 124 762 027; i) Medicare Australia; and j) relevant statistical research entities. (s 35) HHS Service Agreements do not currently specify restrictions on storage of health information data, but do specify that such a requirement may be imposed in an amended Schedule 4. (Service Agreements)			health information data, but do specify that such a requirement may be imposed in an amended Schedule 4.	
7.	***Quality Assurance Committees*** under Part 6, Division 1, *Hospital and Health Boards Act 2011*	Quality assurance committees may be established by health services, a professional association, society, college or other entity whose functions relate to the provision of health services or to the providers of health services; the Chief	A report furnished, or information made available, by a committee, must not disclose the identity of an individual who is a provider or recipient of health services unless the individual has consented in writing to that disclosure. (s 84)	How long identified information can be stored is not specified.	Disclosure and transfer of reports and documents held by a Quality Assurance Committee are governed by s 85. This section does not however cover transfer to a third party for the purposes	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Executive and licensees of a private health facility. (s 82)			of extending storage duration. (s 85)		
8.	***Health (Drugs and Poisons) Regulation 1996***	A person dispenses or supplies a controlled drug is responsible for personally entering the details of each transaction in the controlled drugs record. (reg 87)	A person dispenses or supplies a controlled drug is responsible for storing controlled drug records. (reg 87)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The pharmacist or person must include in its entry the details of the same, the details of the recipient, the details of the drug and the details of the remaining stock. (reg 87)	How long researchers must store data once a study is closed is not specified.
9.	***Mental Health Act 2016*** **Chief Psychiatrist** means the Chief Psychiatrist appointed by the Governor in Council	The Chief Psychiatrist is responsible for establishing and maintaining a records system for keeping electronic records of: a) advance health directives; b) enduring powers of attorney for a personal matter; and c) appointments of nominated support persons. (s 225)	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The records system must be capable of being kept in electronic form. (s 225)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
10.	***Information Privacy Act 2009 (IP Act)***[9] ***National Privacy Principles (NPPs)*** under Schedule 4 of the *IP Act* **Health agencies** means the Health Department or a Hospital and Health Service. The Act deals with secondary obligations attaching to personal information collected by a health agency.	Who is responsible for health information data is not specified.	Health agencies must ensure the security of personal information held, including taking reasonable steps to protect the personal information from misuse, loss and unauthorised access, modification or disclosure. (NPP 4) Third parties can store personal information of health agencies. When entering into service arrangements with an entity other than an agency, the agency is generally required to take all reasonable steps to ensure that the contracted service provider is required to comply with the IP Act if the contracted service provider will, among other things, deal with personal information for the contracting agency. (s 35)	How long identified information can be stored is not specified.	Health agencies must not store, handle or transfer health information in a way that is inconsistent with the NPPs. (s 31(2))	Health agencies must not store health information in a way that is inconsistent with the NPPs. (s 31(2))	How long researchers must store data once a study is closed is not specified.

[9] Health agencies must comply with the National Privacy Principles (NPPs) (s 31(1), *Information Privacy Act 2009* (Qld)).

Table Four: New South Wales

Table Four summarises the New South Wales the legislation which is relevant to the collection and storage health information. Some, but not all of the legislation summarised in Table Four is relevant to establishing a national CQR as a quality assurance activity or as a pilot within a research framework. QAAs are subject to special protections that do not otherwise apply to all research conducted for the purposes of maintaining quality and safety or continuous improvements in the health care sector.

CQRs as a Quality assurance activity

In New South Wales, protected quality assurance activities engaged in by public hospitals or establishment, college and associations are established under the *Health Administration Act 1982*.

Entities that are covered by the *Health Administration Act 1982* are also eligible to apply for a declaration under the *Health Insurance Act 1973*, however the Commonwealth qualified privilege scheme offers similar protections to the *Health Administration Act 1982* so this additional step may not be necessary.

CQRs within a research framework

An individual or organisation who wishes to establish a CQR as a pilot and/or for development as a national CQR within a research framework requires an identifiable custodian to operate the CQR with approval by a human research ethics committee and acknowledgment by the contributing institutions of their responsibilities as provided in the National Statement. This may require local site specific assessment review by the authorising institution.

Individuals and organisations based in NSW should also refer to the Statutory Guidelines on Research made under the *Health Records and Information Privacy Act 2002.*

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
New South Wales							
1.	***Public Health Act 2010*** ***Public Health Regulation 2012*** **Secretary** means the Secretary of the Ministry of Health	A registered medical practitioner is responsible for recording particulars of **Category 1 and 2 conditions** and notifying the Secretary. (s 54)	Registered health practitioners are required to record information, thereafter the results are to be stored by the Secretary. (s 54)	The registered medical practitioner must keep any such particulars for seven years. (reg 38) The Public Health Act does not specify the duration for which the data may be stored beyond this.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A registered medical practitioner must not include a patient's name or address in information provided in relation to a Category 5 condition. (s 56(1))	The Public Health Act does not specify the duration for which researchers may store the data.[10]
		If a pathology test is carried out that has a positive result for a **Category 3 Condition**, the person who certifies the test results is responsible for sending the Secretary a report of that fact. (s 55)	The persons responsible for certifying results at pathology laboratories are required to report positive results for Category 3 conditions, thereafter the results are to be stored by the Secretary. (s 55)	How long identified information can be stored is not specified.[11]	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A registered medical practitioner must not include a patient's name or address in information provided in relation to a Category 5 condition. (s 56(1))	How long researchers must store data once a study is closed is not specified.

[10] Researchers from the National Health and Medical Research Council must maintain records in accordance with the relevant Records Authority issued by the National Archives of Australia (Archives Act 1983)

[11] The Australian Privacy Principles (see Table One: Commonwealth) require that when personal information is no longer required for the purpose for which is was used, it must be destroyed or de-identified.

Legislation		Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		A **public health or disease register** may be established and maintained for any of the following purposes: a) to facilitate care, treatment and follow up of persons who have diseases or have been exposed to diseases, b) to facilitate identification of sources of infection and control of outbreaks, c) to facilitate identification and monitoring of risk factors for diseases or conditions that have a substantial adverse impact on the population, d) to facilitate measurement and monitoring of outcomes of specified population health interventions, e) to facilitate identification and monitoring of exposure to chemicals or other	The Secretary may enter into an agreement or arrangement with any other person for the establishment or maintenance, or both, of any a public health or disease register. A public health organisation must, if directed to do so in writing by the Secretary, provide information for the purposes of any such register (s 98).	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A public health or disease register must not contain identifying particulars of a person, except with the consent of the person. (s 98(5)) The Secretary or their delegate may provide personal information about a person to a health records linkage organisation for the purpose of establishing and providing a unique identifier number to be used for the purposes of a public health or disease register. (s 98(6))	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		environmental factors that impact/ may impact, adversely on health of individuals, and f) any other purpose prescribed by regulations. (s 97)					
		Hospital CEO is responsible for notifying the Secretary of notifiable diseases and provide additional information as and when requested by the Secretary, (s 83) Data reported to the secretary under s 83 includes the **Cancer Notification Forms**, information in relation to congenital diseases and **Doctor/Hospital Notification Forms.** (reg 41)	The Secretary may enter into an agreement or arrangement with any other person for the establishment or maintenance, or both, of any a register of notifiable diseases. A public health organisation must, if directed to do so in writing by the Secretary, provide information for the purposes of any such register. (s 98)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A public health or disease register must not contain identifying particulars of a person, except with the consent of the person. (s 98(5)) The Secretary or a person authorised in writing by the Secretary may provide personal information about a person to a health records linkage organisation for the purpose of establishing and providing a unique identifier number to be used for the purposes of a public health or disease register. (s 98(6))	How long researchers must store data once a study is closed is not specified.
2.	***Declaration of State of Emergency: COVID-19***	The NSW Minister for Health has powers under the Public Health Act to deal with public	The NSW Minister for Health will necessarily collect and use	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional	The Declaration and associated directions do not specify a format for	How long researchers must store data once a

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	under the *Public Health Act 2010*	health risks generally. He may take action and make orders as he considers necessary to deal with the risk of COVID-19, which may include segregating or isolating people or preventing access to an area.	information relating to the public health risk.		storage duration is not specified.	storing records or information obtained in the course of exercising the powers under the directions .	study is closed is not specified.
3.	***Private Health Facilities Act 2007*** ***Private Health Facilities Regulations 2017*** **Secretary** means the Secretary of the Ministry of Health	'Appropriate staff' of a private health facility are responsible for maintaining clinical records for all patients. (s 5; sch 1, reg 12(1)) Prior to a private health facility ceasing to operate, the licensee is responsible for making and apprising the Secretary of arrangements for the safe keeping of records in line with the *Health Records and Information Privacy Act 2002* (NSW). (sch 1, regs 12(3)) The Secretary of the Ministry of Health may impose additional license conditions on individual facilities as they see fit. (s 7(2))	The Private Health Facilities Regulations allow the following committees to store data in limited circumstances: a) the Special Committee Investigating Deaths Under Anaesthesia; b) the Collaborating Hospitals' Audit of Surgical Mortality Committee; c) the NSW Maternal and Perinatal Mortality Review Committee; and d) the NSW Mental Health Sentinel Events Review Committee. (reg 18)	How long identified information can be stored is not specified, however the Secretary of the Ministry of Health may impose additional license conditions on individual facilities as they see fit. (s 7(2))	The Private Health Facilities Regulations allow identified health information to be transferred to the following committees in limited circumstances: a) the Special Committee Investigating Deaths Under Anaesthesia; b) the Collaborating Hospitals' Audit of Surgical Mortality Committee; c) the NSW Maternal and Perinatal Mortality Review Committee; and d) the NSW Mental Health Sentinel Events Review Committee. (reg 18)	The licensee of a private health facility must provide a statistical statement in the form approved by the Secretary of the Ministry of Health within 14 days after the end of each month. (reg 23) Neither the Private Health Facilities Act nor the Private Health Facilities Regulations specify a form for other forms of health information data. The Secretary of the Ministry of Health may impose additional license conditions on individual facilities as they see fit. (s 7(2))	How long researchers must store data once a study is closed is not specified, however the Secretary may impose additional license conditions on individual facilities as they see fit. (s 7(2))

Legislation		Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			Neither the Private Health Facilities Act nor the Private Health Facilities Regulations specify any additional parties who can store health information data, however the Secretary may impose additional license conditions on individual facilities as they see fit. (s 7(2))		A copy of all patient records must be transferred to any receiving facilities of transferred patients (sch 1, reg 19). The Secretary may direct a private health facility to engage an external expert. (s 57) This may involve identified health information being transferred to another location for an additional storage duration. The Secretary of the Ministry of Health may impose additional license conditions on individual facilities as they see fit. (s 7(2))		
		Maternity class private health facilities are responsible for maintaining a **birth register** that records the details of every child born at the facility. (sch 2, reg 42)	Who can store health information data is not specified	Maternity class private health facilities must retain a child's record for at least 25 years after their birth. (sch 2, reg 42)	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

Legislation		Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Surgical class private health facilities are responsible for maintaining a **procedure register** that records the details of every surgical procedure carried out. (sch 2, reg 81)	Who can store health information data is not specified	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.
		Private health facilities are responsible for maintaining a **register of patients at the facility**. (s 38; reg 15)	Who can store health information data is not specified	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The register of patients must be kept in a form approved by the Secretary. (s 38; reg 15)	How long researchers must store data once a study is closed is not specified.
		A private health facility is responsible for convening a **root cause analysis team** to consider the root cause of all reportable incidents. (s 42)	Root cause analysis teams and in limited circumstances the following committees may store root cause analysis data: a) the Special Committee Investigating Deaths Under Anaesthesia; b) the Collaborating Hospitals' Audit of Surgical Mortality Committee; c) the NSW Maternal and Perinatal Mortality Review Committee; and	How long identified information can be stored is not specified.	Root cause analysis teams may disclose identified information to the following committees in limited circumstances: a) the Special Committee Investigating Deaths Under Anaesthesia; b) the Collaborating Hospitals' Audit of Surgical Mortality Committee; c) the NSW Maternal and Perinatal Mortality Review Committee; and d) the NSW Mental Health Sentinel Events Review Committee. (reg 18)	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			d) the NSW Mental Health Sentinel Events Review Committee. (reg 18)		Otherwise, root cause analysis teams may not disclose identified information, or information that may lead to identification, without written consent. (ss 43 and 45)		
4.	***Statutory Guidelines on Research*** under the *Health Records and Information Privacy Act 2002* These guidelines apply to every organisation that is a health service provider or that collects, holds or uses health information and is subject to the *Health Records and Information Privacy Act 2002.*	An organisation may disclose health information for the purpose of research or statistical compilation or analysis where reasonably necessary to achieve that purpose, or for the purpose of research of managing health services, and where approved by a Human Research Ethics Community. (see 1.2, 3.3 and 5, *Statutory guidelines on the management of health services*)	Wherever possible, original data must be retained in the department or research unit in which they were generated. Individual researchers should be able to hold copies of the data for their own use. (see 2.9.5(m) and Appendix B (2.4))	Data must be retained for sufficient time to allow reference. The recommended minimum period is at least five years from the date of publication but for clinical research, fifteen years may be more appropriate. (see 2.9.5(m) and Appendix B (2.3))	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A version of the data should be kept in a format that allows disclosure to third parties without breaching confidentiality (e.g. de-identified). (see 2.9.5(m) and Appendix B (2.5)) Where data is obtained from limited access databases, the researcher must retain a written record of key information of the original data. (see 2.9.5(m) and Appendix B (2.10))	Data must be retained for sufficient time to allow reference. The recommended minimum period is at least five years from the date of publication but for clinical research, fifteen years may be more appropriate. (see 2.9.5(m) and Appendix B (2.3))

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
5.	***Health Administration Act 1982*** ***Health Administration Regulation 2015*** **Secretary** means the Secretary of the Ministry of Health	The Secretary may inquire into the nature, extent and standards of the health services, facilities and personnel required to meet the health needs of the people of New South Wales and to determine the cost of meeting those needs. (s 8) Quality assurance committees are responsible for assessing and evaluating health services, report and make recommendations concerning those services and monitor the implementation of recommendations. (s 20E) Root cause analysis teams are responsible for investigating and considering reportable incidents. (Division 6C *Act*)	Health officials may disclose health information to other health officials to enable them to exercise their functions where such a disclosure is in the public interest. (s 23A)	How long identified information can be stored is not specified.	Root cause analysis teams and quality assurance committees may not disclose identified health information except in limited circumstances (ss 20G, 20P and 22) including, with secretarial approval, where: a) the information is required for the purpose of medical research and the Secretary is satisfied that the research is being conducted in accordance with relevant guidelines; and b) the disclosure is made to the Centre for Health Record Linkage (CHeReL), or similar organisations for funding, management, planning or evaluation purposes. (reg 17) Root cause analysis teams may disclose identified health information to the following committees in limited circumstances:	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

Legislation		Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
					a) the Special Committee Investigating Deaths Under Anaesthesia; b) the Collaborating Hospitals' Audit of Surgical Mortality Committee; c) the NSW Maternal and Perinatal Mortality Review Committee; and d) the chief executive offices of relevant health services organisations. (reg 14)		
6.	***Poisons and Therapeutic Goods Regulation 2008***	A pharmacist or practitioner who supplies a restricted substance on prescription is responsible for keeping records of the transactions. (regs 55, 55, 56 and 57)	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Records must include details about the transaction; the recipient, and any person or animal who will ultimately use the substance; the supplier; and the remaining supply of the substance. (regs 55, 55, 56 and 57)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
7.	***Assisted Reproductive Technology Act 2007*** **Secretary** means the Secretary of the Ministry of Health	An ART provider is responsible for keeping detailed records of each gamete or embryo, and the uses that have been made of any such gamete or embryo, any recipients of ART treatment, and any offspring born as a result of ART treatment. (s 31) The Secretary is responsible for establishing and maintaining a central register of information about donors and offspring. (ss 32A, 32C)	The Secretary and the Registrar of Births, Deaths and Marriages may share information for the purpose of enabling or assisting the Secretary to ensure the completeness and accuracy of the central register. (s 35) The Secretary may disclose health information in limited circumstances to a donor, an adult offspring of a donor, a woman who has undergone ART treatment using a donated gamete and a parent of a child who is an offspring of a donor. (ss 36, 37, 38, 39, 40, 40A, and 40B)	If an ART provider supplies a gamete or an embryo to another ART provider, they must give over copies of appropriate records to the recipient ART provider. (s 32) The ART provider must retain any records for a period of 50 years after the record is made. (s 31(2)) An ART provider must ensure that any pre 2010 record within the ART provider's control is retained by the ART provider in a readily accessible form during the retention period for the record. (s 41O)	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Secretary must remove information from the register that has been provided voluntarily by a person if the person applies, in an approved form, to have the information removed and the Secretary is satisfied that the information is not information that is otherwise required to be on the register. (s 33D)	How long researchers must store data once a study is closed is not specified.
8.	***Health Records and Information Privacy Act 2002*** ***Health Records and Information Privacy Regulation 2017*** ***Health Privacy Principles* (HPPs)** under Part 5 and Sch 1 of the *Health Records and Information Privacy Act 2002.*	The NSW Privacy Commissioner is responsible for conducting research, an collecting and collating information, about any matter relating to the protection of health information and individual privacy. (s 58)	Organisations may disclose health information to a third party in connection with that party's provision of a service to the organisation (HPP5(1)(d)) Organisations may transfer health information outside NSW and Commonwealth jurisdiction in a number	Health information must not be held for longer than is necessary to achieve the purposes for which the information is held and must be disposed of securely. (HPP 5) Note: limits on storage of health information do not apply to information about an individual	Organisations may disclose health information for a secondary purpose in limited circumstances, and may have to take steps to de-identify the information. (HPP 11) Health information must not be held for longer than is necessary to achieve the purposes for which the information is held and must be	Health information must be stored so that it is protected against loss, unauthorised access, use, modifcation or disclosure, and other misuse (HPP5). An organisation may only assign identifiers to individuals where	Health information must not be held for longer than is necessary to achieve the purposes for which the information is held and must be disposed of securely. (HPP 5) Note: limits on storage of health information do not apply to information

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	The Act applies to every organisation that is a health service provider or that collects, holds or uses health information (s 11)	Organisations may collect health information where reasonably necessary (HPP 1)	of circumstances, including where the organisation reasonably believes: a) the recipient of the information is subject to a binding law or contract that upholds similar principles to the Health Privacy Principles espoused in the Act; or b) it has taken reasonable steps to ensure the recipient will not use the information inconsistently with the Health Privacy Principles espouses in the Act (HPP 14) Organisations may use or disclose health information for a secondary purpose in limited circumstances, and may have to take steps to de-identify the information. (HPPs 10-11)	who has been dead for more than 30 years	disposed of securely. (HPP 5) Note: limits on storage of health information do not apply to information about an individual who has been dead for more than 30 years.	reasonably necessary (HPP12). Organisations that hold health information must do so in a way that allows individuals to ascertain whether they hold health information relating to that individual and access details of that information. (HPP 6). An organisation must not include an individual's health record in a linkage system without express consent, except in limited circumstances. For research purposes, linked information may have to be de-identified. (HPP 15)	about an individual who has been dead for more than 30 years.

Legislation		Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Private health service providers are subject to additional requirements under the *Health Records and Information Privacy Act*. (Part 4 *Act*) These requirements also extend to research services conducted by, on behalf of, or pursuant to an agreement with: a) the Ministry of Health, b) the Health c) Administration Corporation, d) a public health organisation or public hospital, or e) the Cancer Institute (NSW). (reg 8A) Note: these research organisations fall into the definition of "health service provider" for the purpose of the Act.	Private health service providers may transfer an individual's health information to third parties with written authority. (s 26(2))	Private health service providers must retain health information relating to an individual: a) for seven years after the last health service was provided; or b) in the case of minors, until the patient turns 25. (s 25) A health service provider who deletes or disposes of health information must keep a record of the name of the individual to whom the health information related, the period covered by it and the date on which it was deleted or disposed of. (s 25(2))	Private health service providers may transfer an individual's health information to third parties with written authority. (s 26(2)) A health service provider who transfers health information to another organisation and does not continue to hold a record of that information must keep a record of the name and address of the organisation to whom or to which it was transferred. (s 25(3))	Formats for storing health information are not specified.	Private health service providers must retain health information relating to an individual: a) for seven years after the last health service was provided; or b) in the case of minors, until the patient turns 25 (s 25). A health service provider who deletes or disposes of health information must keep a record of the name of the individual to whom the health information related, the period covered by it and the date on which it was deleted or disposed of. (s 25(2))

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Multicultural NSW may collect and hold health information for **translation purposes**. Where Multicultural NSW transfers health information to a third party, it must do everything within its power to prevent unauthorised disclosure by that party. (s 17A)	Multicultural NSW may give health information to a third party where necessary. (s 17A)	Multicultural NSW must return or destroy health information when satisfied the documents are no longer required for the provision of a translation service. (s 17A)	Multicultural NSW may give health information to a third party where necessary. (s 17A)	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.
9.	***Privacy and Personal Information Protection Act 1998***	Public sector agencies are responsible for keeping public registers and maintaining appropriate security. [12] (Part 6)	Public sector agencies may require persons to provide a statutory declaration as to the intended use of personal information they apply to inspect. (s 57(2))	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.
10.	***State Records Act 1998*** ***State Records Regulation 2015*** **Chief Executive** means the chief executive of any public office responsible for a State record.	The Chief Executive is responsible for ensuring ensure that the relevant public office complies with the State Records Act 1998 and State Records Regulation 2015. (s 10)	Where possession of health information is transferred to a third party, the chief executive must ensure arrangements are made for the safe keeping, proper preservation and due return of the record. (s 11)	The State Archives and Records Authority must not dispose health information without the chief executive's consent. (s 24)	Once health information is no longer in use for official purposes, the State Archives and Records Authority is entitled to take control of it. (s 27)	Health information may be stored in electronic format so long as the chief executive ensures that the information remains able to be produced or made available. (s 14(1))	A researcher must not dispose of health information kept a for any purpose of a public office except in limited circumstances. (s 21; see also Sch 2 *Regulations*)

[12] This is the position for all public sector authorities in NSW.

Legislation		Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		The Chief Executive is responsible for making arrangements with State Archives and Records Authority for reporting on the implementation of records management programs and monitoring of these programs, and for ensuring arrangements for safe keeping, proper preservation and due return of records. (ss 11, 12(4))	State Archives and Records Authority must be allowed such access as is necessary to monitor compliance with the Act and Regulations. (s 15)				

Table Five: Victoria

Table Five summarises the Victorian legislation which is relevant to the collection and storage of health information. Some, but not all of the legislation summarised in Table Five is relevant to establishing a national CQR as a quality assurance activity or as a pilot within a research framework. QAAs are subject to special protections that do not otherwise apply to all research conducted for the purposes of maintaining quality and safety or continuous improvements in the health care sector.

CQRs as a Quality assurance activity

In Victoria, quality assurance activities are established under the *Health Services Act 1988*. Health information obtained as part of a quality assurance activity cannot be disclosed for reasons other than for a purpose related to the activity.

Entities that are covered by the *Health Services Act* 1988 may also be eligible to apply for a declaration under the *Health Insurance Act 1973*, however the Commonwealth qualified privilege scheme offers similar protections to the *Health Services Act 1988* so this additional step may not be necessary.

CQRs within a research framework

An individual or organisation who wishes to establish a CQR as a pilot and/or for development as a national CQR within a research framework requires an identifiable custodian to operate the CQR with approval by a human research ethics and acknowledgment by the contributing institutions of their responsibilities as provided in the National Statement. This may require local site specific assessment review by the authorising institution.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
Victoria							
1.	***Mental Health Act 2014*** **Chief Psychiatrist** means the Chief Psychiatrist employed by the Secretary of the Department of Health and Human services. **Secretary** means the Secretary of the Department of Health and Human Services	The Secretary is responsible for collecting, compiling and analysing data about the provision of mental health services for purposes related to its functioning. (s 118) The Secretary must be notified of prescribed events regarding vulnerable healthcare recipients. (ss 40, 41, 43, 50, 59, 60, 63, 64, 65, 66, 96, 107, 277, 283, 285, 290, 293, 297, 309, 352) The Chief Psychiatrist or in some cases, the Secretary to the Department of Justice and Regulation, the Secretary, or the Chief Commissioner of Police is notified after certain notifiable events. (ss 99, 348, 349)	The Chief Psychiatrist employed by the Secretary may analyse data, undertake research and publish information about the provision of mental health services and treatment. (s 121) The Secretary may enter into agreements or arrangements with third parties to assist the Chief Psychiatrist. This may involve disclosing health information to these parties. (s 143) Mental health service providers, staff members, contractors, volunteers and board members may only disclose health information about consumers in limited circumstances. (s 346)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Health information may be stored electronically. (s 347)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			A person may only collect or use information from an electronic health information system in limited circumstances. (s 347)				
		The Chief Psychiatrist must submit reports which state the number of **young persons who received one or more courses of electroconvulsive treatment** and provides details of the relevant clinical outcomes. (s 145) The psychiatrist treating a **person who has received or is receiving electroconvulsive treatment, neurosurgery or restrictive intervention** for the treatment of mental illness must provide written reports to the	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Chief Psychiatrist. (s 99)					
2.	***Health Services Act 1988*** ***Health Services (Health Service Establishments) Regulations 2013*** Note: The *Health Legislation Amendment and Repeal Act 2019* will introduce a new Part 6B to the Health Services Act to facilitate the sharing of information between health services, Safer Care Victoria and the Victorian Agency for Health Information. These amendments will commence on 27 August 2020.	The Secretary of the Department of Health is responsible for collecting and analysing data for purposes related to its functioning. (s 10) The Secretary of the Department of Health is responsible for directing public and denominational hospitals, multi-purpose services, registered funded agencies in relation to the accounts and records which should be kept by the hospital and supplied to the Secretary. (ss 24, 42(1)(h), and 115M) The proprietor of a health service establishment is responsible for providing data in relation to each patient to the	A person may not disclose information gained by reason of involvement with a quality assurance committee except where necessary for the performance of that committee's functions. (s 139(3)) A person must not disclose health information except in limited circumstances including: a) to carry out its functions in relation to a health service; b) for approved medical or social research; and c) to the Australian Statistician. (s 141)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The proprietor of a health service establishment must ensure a unit record number is allocated to a patient on or as soon as practicable after admission, except in limited circumstances. (reg 19) Clinical records must contain the patient's unit record number, name, address, date of birth, sex, contact details and clinical details. (reg 22)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Secretary of the Department of Health. (s 110C*;* reg 46) The proprietor of a private hospital is responsible for providing on a monthly basis data about: a) infections and infection control; b) any electroconvulsive treatment; and c) emergency admissions to the Secretary of the Department of Health. (s 110C*;* reg 46) The proprietor of a health service establishment is responsible for notifying the Secretary of the Department of Health of any actual or suspected serious risks to patient health or safety or sentinel					

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		events (s 110D, reg 46A) Health Purchasing Victoria is responsible for maintaining a database of purchasing data of public hospitals and supply markets for access by public hospitals. (s 131) The proprietor of a health service establishment is responsible for ensuring the records are made of pre-admission clinical risk assessments and clinical records generally. (regs 20A and 21)					
		The proprietor of a health service establishment is responsible for maintaining a **patient admission and discharge register.** (s 109, reg 35)	The proprietor of a health service establishment may store a patient admission and discharge register. (s 109, reg 35)	The patient admission and discharge register must be retained for 7 years (reg 35).	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The patient admission and discharge register must be in writing and contain each patient's unit record number, name, sex, contact details, date of birth, date of admission and	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
						discharge, description of care received and status of the patient at discharge, and any transfer details (s 109, reg 35*)*	
		The proprietor of a health service establishment is responsible for maintaining a **staff register.** (s 109, reg 36*)*	The proprietor of a health service establishment may store a staff register. (s 109, reg 36)	The staff register must be retained for 2 years (reg 36).	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The staff register must be in writing and contain each staff member's name, date of birth, designation, qualifications and any registration details (s 109, reg 36*)*	How long researchers must store data once a study is closed is not specified.
		The proprietor of a health service establishment at which surgical or endoscopy services may be carried on is responsible for maintaining an **operation theatre register.** (s 109, reg 37*)*	The proprietor of a health service establishment may store an operation theatre register. (s 109, reg 37*)*	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The operation theatre register must be in writing and contain the date and time of each procedure, the unit record number of each patient, the full name, sex and date of birth of each patient, the nature of the procedure, he names of all attending practitioners and theatre staff and remarks concerning the outcome and any	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
						complications. (reg 37)	
		The proprietor of a health service establishment at which obstetric services may be carried on is responsible for maintaining a **birth register.** (s 109, reg 38*)*	The proprietor of a health service establishment may store a birth register. (s 109, reg 38*)*	The birth register must be retained for at least 25 years after the date of the last entry. (reg 38)	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The birth register must be in writing and contain the date and time of the birth, the name of and unit record number of the mother, the sex of the infant and the names of all health care personnel in attendance. (reg 38)	How long researchers must store data once a study is closed is not specified.
		The proprietor of a health service establishment is responsible for ensuring **quality and safety data** is recorded. (reg 48) The proprietor of a health service establishment must ensure patient experience data and staff safety culture survey data is collected and made available for use. (regs 49 and 50)	The proprietor of a health service establishment may store quality and safety data. (reg 48)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Quality and safety data must be recorded in writing, reviewed at least every 3 months and contain: a) information in relation to decisions and actions taken for the purposes of improving the quality and safety of health services; and b) information in relation to all adverse and	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
						sentinel events, all mortality and morbidity occurrences, compliance with internal protocols and results from patient experience and staff safety surveys. (reg 48)	
3.	***Improving Cancer Outcomes Act 2014*** ***Improving Cancer Outcomes (Screening Reporting) Regulations 2015*** ***Improving Cancer Outcomes (Diagnosis) Regulations 2015*** **Secretary** means the Secretary to the Department of Health and Human Services.	The Secretary is empowered to maintain a register of information collected by the Secretary under this Act. (s 4) The Secretary may delegate that power to a Department of Health employee or contractor. (s 5) The Secretary must not enter into an agreement with an service provider to perform functions under the Act unless satisfied that the agreement imposes obligations on the	Prescribed persons must report to the Secretary if an individual undergoes cancer screening of a prescribed type or is diagnosed with cancer of a prescribed type. (ss 8 and 9) The Secretary may then direct the person or organisation to provide further information. (s 10) The Secretary may use and disclose health information about an individual collected under this	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The report of the cancer screening must: a) be in the prescribed form; and b) be made within the prescribed time; and c) include the prescribed information. (s 8, s 9, see *Regulations* for details)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		service provider relating to the confidentiality, privacy and security of any information to be used or collected that comply with this Act and the Health Privacy Principles. (s 6)	Act for the purpose of performing the Secretary's functions under this Act and where certain criteria are met. (ss 14, 15) The Secretary may collect information about Victorian residents from cancer screening registers and cancer registers maintained in other jurisdictions. (s 11)				
4.	***Disability Act 2006*** **Secretary** means the Secretary of the Department of Health and Human Services. **Department** means the Department of Health and Human Services.	The Secretary must ensure that the Department maintains information systems for the purposes of enabling: a) the planning, monitoring, evaluating, provision and funding of disability services for persons with a disability; b) the Secretary to achieve the objectives and perform the	The Secretary is responsible for overseeing the storage of information provided to and maintained by the Department. (s 39)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		functions conferred on the Secretary under this Act or any other law relating to disability. (s 39)					
5.	***Public Health and Wellbeing Act 2008*** **Secretary** means the secretary to the Department of Health and Human Services. **Chief Health Officer** means the registered medical practitioner appointed by the Secretary to be the Chief Health Officer.	A registered medical practitioner or pathologist who becomes aware of a relevant notifiable fact must notify the Chief Health Officer; and the person on whom the examination or test was conducted. Registered practitioners may be required to provide information to the Chief Health Officer as and when requested. (ss 127, 128, 129, and 130)	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.
		The **Consultative Council on Obstetric and Paediatric Mortality and Morbidity (CCOPMM)**	a) The CCOPMM are responsible for storing data collected in	How long identified information can be stored is not specified. However, The CCOPMM may prepare and issue	The CCOPMM may provide health information data to health service providers. (s 46)	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		conduct a perinatal data collection unit for the purpose of: a) collecting, studying, researching and interpreting information on and in relation to births in Victoria; b) identifying and monitoring trends in respect of perinatal health including birth defects and disabilities; c) providing information to the Secretary on the requirements for and the planning of neonatal care units; d) providing information for research into the epidemiology of perinatal health including birth defects and disabilities; e) establishing and maintaining a register of birth defects and disabilities (s 46)	accordance with its purpose and functions. The CCOPMM may provide this data to health service providers (s 46)	guidelines on this point. (s 46A)			

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		The Chairperson of CCOPMM may request a person who provided care or services to a child before the child's death to provide general or specific information which the Chairperson of CCOPMM considers is necessary to enable CCOPMM to perform its function. (s 47)					
		A registered medical practitioner must notify the Secretary if they have reasonable grounds to believe that a patient has, or may have, a **notifiable condition**; or has, or may have, died with a notifiable condition. Health services and pathology services must implement processes to ensure compliance with reporting obligations. (s 129).	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
6.	***Health Complaints Act 2016*** **Commissioner** means the Health Complaints Commissioner appointed under section 111 of the Act.	If a complaint is made to the Commissioner, the Commissioner must make a written record on receiving the complaint. (s 10)	The Commissioner and any delegates are responsible for storing information. (s 118)	How long identified information can be stored is not specified.	The Act includes provisions in relation to the disclosure of a health complaint to the health service provider about whom the complaint is made (s 17) and other entities as and when required. (Part 13)	The record of the complaint must include the date that the complaint was received by the Commissioner. (s 10) As soon as possible after a decision is made under section 13 to deal with a complaint, the Commissioner must seek the agreement of the complainant to a description of the complaint. (s 15)	How long researchers must store data once a study is closed is not specified.
7.	***Public Records Act 1973*** **Public records** include any records made by public officers in Victoria. **Keeper of Public Records** means the person employed under the in that position.	The **Keeper of Public Records** is responsible for the preservation and security of public records under his control; the logical and orderly classification of such records and the publication of lists indexes and other guides facilitating their use; the duplication and reproduction of public records for	The **Keeper of Public Records** may store public records. (ss 6 and 7)	Once held by the Public Record Office, public records must be kept for up to 30 years. (s 10)	Where a public record in the possession of a public office other than the Public Record Office has been in existence as a public record for 25 years and has ceased to be required to be readily available for the purposes of a public office, the public office must transfer the record	The Keeper of Public Records shall establish standards for the efficient management of public records, including in relation to management of public records. (s 12)	There are no specific provisions related to public records used for research purposes, however public records may be stored for up to 30 years. (s 10)

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		official and other purposes; and the authentication of copies of and extracts from public records required as evidence in legal proceedings or for other purposes. (s 7)			to the custody of the Public Record Office. (s 8A)		
8.	***Victorian Data sharing Act 2017*** ***De-identification Guideline*** *under s 33 of the Act* *The Act applies to departments, independent and oversight bodies, and other types of government bodies in Victoria as either data sharing, data analytics or designated bodies.*	The Chief Data Officer is responsible for: a) conducting data integration and data analytics work; b) building capability in data analytics across the public sector; c) leading and coordinate cross-jurisdictional data sharing and data integration; d) making data available to data sharing bodies and designated bodies; and e) collaborating with data sharing	Data sharing and designated bodies may disclose identifiable data to the Chief Data Officer in response to a request. (ss 8, 11 and 15) The Chief Data Officer may disclose may disclose identifiable data for the purposes of data integration. (s 16*)* The Chief Data Officer or data analytics body may collect, hold, manage, and use identifiable data received from data sharing and designated bodies for the purpose of data	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Chief Data Officer or data analytics body must take reasonable steps to de-identify data before using it for data analytics work and must ensure data is fully de-identified before any disclosure of data analytics results. (ss 18 and 19) Physical and logical data separation protocols must be implemented between data integration and analytics teams, and between linkage and content integration	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		bodies and designated bodies. (s 7) The Chief Data Officer or data analytics body is responsible for collecting, holding, managing, and using identifiable data received from data sharing and designated bodies for the purpose of data integration. (s 17)	integration. (s 17) Analysts accessing data in the analytics environment must be trusted users with the appropriate security vetting, technical capability, and privacy and security training. (6.14, *Guideline*) Authorised, external researchers may in certain circumstances be provided with access to 'de-identified' data.(6.14, *Guideline*)			teams. (5.1, *Guideline*)	
9.	***Health Records Act 2001*** ***Health Privacy Principles*** **Organisations** include public and private persons, bodies corporate, partnerships, trusts and any other unincorporated association or body	Organisations are responsible for collecting health information where reasonably necessary to achieve a number of purposes, including with the person's consent, for research purposes, to lessen serious threats or for law enforcement or	Health service providers may transfer an individual's health information to third parties with written authority. (s 30) Organisations may use or disclose health information for a secondary purpose in limited	Health information must be destroyed or permanently de-identified once it is no longer necessary to achieve the purposes for which the information is held. (HPP 4.5*;* see also s 21) A health service provider who	Health information must be destroyed or permanently de-identified once it is no longer necessary to achieve the purposes for which the information is held. (HPP 4.5*;* see also s 21) Health service providers may	Organisations must store health information in a way that allows an individual to ascertain whether they hold health information relating to that individual and access details of that information. (s 44*;* HPP 5*)*	Health information must be destroyed or permanently de-identified once it is no longer necessary to achieve the purposes for which the information is held. (HPP 4.5*;* see also s 21)

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	that is a health service provider or collects, holds or uses health information.	legal reasons. (HHP 1)	circumstances, and may have to take steps to de-identify the information. (HPP 2) An organisation may only transfer health information outside Victoria in a number of circumstances, including where the organisation reasonably believes a) the recipient of the information is subject to a binding law or contract that upholds similar principles to the Health Privacy Principles, or b) it has taken reasonable steps to ensure the recipient will not use the information inconsistently with the Health Privacy Principles espouses in the Act. (HPP 14)	deletes health information must keep a record of the name of the individual to whom the health information related, the period covered by it and the date on which it was deleted. (HPP 4.3*;* see also s 21)	transfer an individual's health information to third parties with written authority. (s 30) A health service provider who transfers health information to another organisation and does not continue to hold a record of that information must keep a record of the name and address of the organisation to whom or to which it was transferred. (HPP 4.4*;* see also s 21)	Health information must be stored so that it is protected against misuse, loss, unauthorised access, modification or disclosure. (HPP 4.1*;* see also s 21) An organisation may only assign identifiers to individuals where reasonably necessary. (HPP 7*;* see also s 21)	
10.	***Statutory Guidelines on Research***	Who is responsible for health information data is not specified.	Wherever possible, original data must be retained in the department or	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location	Health information may be stored electronically. (Appendix 3, s 2)	Data must be retained for sufficient time to allow reference. The

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	under s 22 of the *Health Records Act 2001.* Note: The Guidelines operate as an exception to the HPPs.		research unit in which they were generated. Individual researchers should be able to hold copies of the data for their own use. (Appendix 3, 2.4) An organisation may disclose health information for the purpose of research or statistical compilation or analysis where reasonably necessary to achieve that purpose and approved by a Human Research Ethics Committee. (1.2 – 1.4)		for additional storage duration is not specified.	Health information should be stored in a durable and appropriately referenced format that complies with the Australian Standard on Personal Privacy Protection. (Appendix 3, s 2.2) Identified health information may only be collected if the collection is necessary for research, or statistical compilation or analysis, in the public interest, and the purpose cannot be served using deidentified date or with consent. (HPP 1.2(e))	recommended minimum period is at least five years from the date of publication but for clinical research, fifteen years may be more appropriate. (Appendix 3, s 2.3)
11.	***Privacy and Data Protection Act 2014***	Health information is excluded from the scope of the Act and the Information Privacy Principles contained in Schedule 1.					

Table Six: Australian Capital Territory

Table Six summarises the ACT legislation which is relevant to the collection and storage of health information. Some, but not all of the legislation summarised in Table Six is relevant to establishing a national CQR as a quality assurance activity or as a pilot within a research framework. QAAs are subject to special protections that do not otherwise apply to all research conducted for the purposes of maintaining quality and safety or continuous improvements in the health care sector.

CQR as a Quality assurance activity

In the ACT, protected quality assurance activities engaged in by all health facilities are established under the *Health Act 1993*. Entities that are covered by the *Health Act 1993* may also be eligible to apply for a declaration under the *Health Insurance Act 1973*, however the Commonwealth qualified privilege scheme offers similar protections to the *Health Act 1993* so this additional step may not be necessary.

CQRs within a research framework

An individual or organisation who wishes to establish a CQR as a pilot and/or for development as a national CQR within a research framework requires an identifiable custodian to operate the CQR with approval by a human research ethics committee and acknowledgment by the contributing institutions of their responsibilities as provided in the National Statement. This may require local site specific assessment review by the authorising institution.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
Australian Capital Territory							
1.	***Public Health Act 1997*** ***Public Health Regulation 2000*** ***Reporting of Notifiable Conditions Code of Practice 2017*** *under ss 20 and 133 of the Public Health Act 1997* **Chief Health Officer** means the person appointed by the Minister of Health in that role.	The Chief Health Officer is responsible for information about public health indicators including in respect of morbidity and mortality, and notifiable conditions. (s 10) The Chief Health Officer, or a person authorised in writing by the chief health officer, may obtain access to and take copies of information about a child's immunisation status where necessary for the regulation or to conduct an epidemiological study. (reg 11)	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified. [13]
		Information acquired by the Territory as a result of notification of **notifiable conditions or public health hazards** may be used for: a) the prevention and control of notifiable conditions;	Where the following delegations have reasonable grounds to believe a relevant person has, may have, or had at the time of their death, a notifiable condition, they must notify the chief health officer as soon as possible:	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A person may only disclose identifiable information about a person with a notifiable condition, or any notifying party, for the purposes of the Act or another law of the Commonwealth, or any State or Territory, authorised under a	How long researchers must store data once a study is closed is not specified.

[13] Research studies funded by the National Health and Medical Research Council must maintain records in accordance with the National Statement – requirement for human research and relevant Records Authority issued by the National Archives of Australia (Archives Act 1983).

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		b) the prevention and control of risks to public health generally; and c) research related to public health. (s 109)	a) Any doctor or nurse practitioner in relation to a patient (s 102A; 2.1, *Code*); b) Any pathologist, and either the person in charge of the relevant hospital laboratory, or the pathologist's employer, in relation to the results of a specimen tested in the ACT or from an ACT resident (s 103; 2.2, *Code*); c) The person in charge of a hospital in relation to an in-patient (s 104; 2.3, *Code*); d) Any counsellor in relation to a person they have counselled (s 105(1); 2.4, *Code*); and e) any person responsible for the care, support or education of someone else in relation to that person. (s 105(2); 2.4, *Code*)			code of practice, or with consent. (s 110) All written notifications should use the Report of Notifiable Condition or Related Death Form. (3.5.3, *Code*)	

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			A person authorised as an authorised officer by the chief health officer who believes a person may have a notifiable condition may request the person provide personal information and information about potential exposure and transmission of the notifiable condition. (s 106) A person must not make an assertion to a contact of a third person that the third person has a transmissible notifiable condition without consent, except in limited circumstances. (s 107) Any person who has reasonable grounds for believing a contaminant or organism poses a significant public health hazard must notify the chief health officer. (s 112)				
		The Chief Health Officer must maintain a **cancer register**. (reg 46)	The following people must give the chief health officer written notice where they conduct a test indicating the	How long identified information can be stored is not specified.	The chief health officer may disclose health information on the cancer register to the person responsible for	The Chief Health Officer may only disclose information on the cancer register to persons other than researchers and	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			presence of cancer, diagnose a relevant person with cancer or treat a relevant person for cancer: a) Any person responsible for the day-to-day control of a laboratory, in relation to the results of a specimen from an ACT resident (reg 42); and b) any person responsible for the day-to-day control of a hospital or nursing home in the ACT in relation to a patient or resident (reg 43), except where cancer has been notified within the previous year. The chief health officer may disclose health information on the cancer register to the person responsible for maintaining the cancer registry of the State or Territory of a relevant person's usual residence. (reg 47)		maintaining the cancer registry of the State or Territory of a relevant person's usual residence. (reg 47) The Public Health Act, the Public Health Regulation and the Reporting of Notifiable Conditions Code of Practice are otherwise silent on transferring cancer register health information for additional storage duration.	persons responsible for maintaining cancer registers where the relevant person, notifying party and any doctors are de-identified. (reg 47(3))	

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			The chief health officer may disclose health information on the cancer register to an approved person engaged in the collection of statistics or medical research. (reg 47)				
2.	***Public Health (Emergency) Declaration 2020 (No 1)*** ***Note: Directions made pursuant to the Declarations are evolving at a rapid rate.***	The public health risk to the ACT community posed by coronavirus disease 2019 (COVID-19) , caused by the novel coronavirus SARS-CoV-2.	While an emergency declaration is in force, the ACT Chief Health Officer may take action or give directions she considers necessary or desirable to alleviate the emergency. This includes: • reduction, removal or destruction of any threat to public health, including directing a person to undergo a medical examination or to remain within a specified area; • segregation or isolation of any person within the ACT; • evacuation of any persons from the ACT; • prevention or permission of access to the ACT; and	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			• direction in relation to the movement of vehicles within the ACT.				
3.	***ACT Health Care Facilities Code of Practice 2001*** *under ss 20 and 133 of the Public Health Act 1997* *This code applies to all licensed health care facilities.*	The licensee of a health care facility must produce and make publicly available an annual report on each facility. (3.1) The licensee of a health care facility must keep a record of each person admitted for treatment in the facility and any babies born in the facility. (5.1)	Who can store health information data is not specified.	Health care records must be retained for minimum of seven years after closure or, where the patient is a child, seven years from the child's eighteenth birthday. (s 5.5)	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A health care facility annual report must contain: the name and location of the facility; the number of professional staff; the number of non-professional staff; the number of patients treated; the number of notifiable incidents reported to the Chief Health Officer; performance measures of morbidity and mortality; the Quality Systems used by the health care facility to protect public safety; any structural changes made to the facility; the number and type of records kept; the details of complaints received; and steps taken to reduce and resolve complaints; and anything else required by the Chief Health Officer (3.2) Health care records must contain the patient's personal details and a detailed history of their treatment. All health	Health care records must be retained for a minimum of seven years after closure or, where the patient is a child, seven years from the child's eighteenth birthday. (s 5.5)

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
						care records must be stored in a secure area of the facility and be protected against unauthorised access. Health care records must be disposed of in a manner that maintains confidentiality. (ss 5.2, 5.3, and 5.6) General records such as accounts, insurance documents, correspondence and other records which may contain health information must be stored and maintained in accordance with AS 4390.1. (5.7*)*	
4.	***Health Act 1993*** ***Director-general*** *means the director-general responsible for ACT Health.*	Any person who has information about a person because of the exercise of a function under the Act must not disclose such information either purposefully or recklessly except as allowed under a Territory law or with consent. (s 125)	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		The CEO of a health facility may give information about a health service to the Chief Executive Medicare; or the auditor-general in limited circumstances. (s 126)					
5.	***Quality Assurance Activities*** *under the Health Act 1993*	Quality Assurance Committees are approved under Part 4 of the *Health Act 1993* (ACT) and include health facility committee, professional organisation committees and special purpose committees. (s 24) A quality assurance committee carrying out a function under the Act may ask anyone to give the committee relevant information, including health information. (s 35(1))	Certain information held by quality assurance committees is protected information and must not be disclosed. (s 35) Quality assurance committees must submit health service reports to: a) for a health facility committee, the CEO of the health facility; or b) for a health professional organisation committee, the CEO of the health professional organisation; or c) for a special purpose QAC committee, the director-general. (s 39) Quality assurance committees may	How long identified information can be stored is not specified.	Disclosure and transfer of reports and documents held by a Quality Assurance Committee are governed by s division 4.5. This section does not cover transfer to a third party for the purposes of extending storage duration.	The Act is silent as to the format in which information held by Quality Assurance Committees should be stored generally. A quality assurance committee must prepare a health service report about any assessment and evaluation of a health service. The report must include: a) details of the health services; b) the results of the assessment and evaluation; c) the committee's conclusions; d) any committee's recommendations. (ss 36 and 38) Quality assurance committees may also be required to provide extraordinary reports and interim reports in writing to the director-	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			share health information with the Coroner's Court, other quality assurance committees, health boards and the health services commissioner, and the Minister where they are satisfied the disclosure would be likely to facilitate the improvement of health services in the ACT. (ss 43, 44, 45, and 46)			general. (ss 38A and 38B) A quality assurance committee must prepare an annual report for the Minister for Health that, amongst other things, addresses why it was in the public interest for secrecy rules to apply to information held by committee members. (s 41)	
6.	***Medicines, Poisons and Therapeutic Goods Act 2008*** ***Medicines, Poisons and Therapeutic Goods Regulation 2008***	The chief health officer may keep a monitored medicines database to record information relating to monitored medicines. (s 97D) The chief health officer may: a) collect and store required information for the database; b) access and use the database to monitor, promote and protect public health and safety; facilitate research; administer, develop and operate the database; and	The chief health officer may allow other jurisdictions, health practitioners, data source entities and other persons to collect and store, access, use and disclose database information. (s 97E) Any person exercising a function under the Act must not make a record of health information or directly or indirectly disclose health information except in limited circumstances. (s 195)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The monitored medicines database may be kept in any form, including electronically, that the chief health officer decides. (s 97D) Controlled medicines registers, dangerous poisons registers, and prohibited substances registers may be kept electronically. (regs 542(2), 741(2), and 776)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		ensure compliance with the Act. (s 97E) Certain persons who possess controlled medicines must keep a controlled medicines register. (reg 540) Certain persons who possess dangerous poisons must keep a dangerous poisons register. (reg 740) Certain persons who possess prohibited substances must keep a prohibited substances register. (reg 775)				Each page in a controlled medicines register, dangerous poisons register, or prohibited substances register must relate to a single form and strength of a controlled medicine, dangerous poisons, or prohibited substance. If a controlled medicines register or dangerous poisons register is kept electronically, a separate record must be used for each form and strength of controlled medicine, dangerous poisons, or prohibited substance kept. (regs 542, 741, and 776) Each entry in a controlled medicines register, dangerous poisons register, or prohibited substances register must detail: a) the nature and date of the dealing; b) the type, form, strength and quantity of the substance; c) the personal details of the other party involved in the dealing;	

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
						d) the details of any prescription, requisition, purchase order; e) where witnessing the administration of medicine is required, the name of the recipient; and f) the quantity of the substance held after the dealing. (regs 543, 742, and 777)	
7.	***Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2019 (No 1)***	Where pharmacists or intern pharmacists conduct vaccinations, they must hold a record of this information and record every vaccination event on the Australian Immunisation register. (Part C(1)) Pharmacists or pharmacies must supply annual records to the Health Protection Service about all pharmacist administered vaccination events. (Part C(2))	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Vaccination records must include: a) Personal details of the patient, b) evidence of the patient's consent, details of the patient's primary medical practitioner, c) details of the vaccine, d) details of the administering pharmacist and their premises, and e) a unique identifying number for the administration event. (Part C(1))	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Pharmacists or pharmacies must supply fortnightly records to the Health Protection Service about all National Immunisation Program funded vaccines.(Part C(2)) Any Adverse Event Following Immunisation must be recorded in the patient's vaccination record and reported to the patient's GP and the ACT Health Immunisation Team. (Part C(4))				Vaccination records should be kept in the format of the Pharmacist Vaccination Record Form or similar. (Part C(2)) Annual records may be supplied electronically. (Part C(2)) Adverse Events Following Immunisations should be reported in the ACT AEFI reporting form. (Part C(4))	
8.	***Mental Health Act 2015*** ***Director general*** *means the director-general responsible for the ACT Civil and Administrative Tribunal Act 2008.*	The director general is authorised to keep the **affected person's register** (s 132). Information may be entered on the register if the person, or someone acting for the person ask the director general or gives consent to the information being recorded and the director general is satisfied that entering the information on the register is necessary for the affected person's safety and wellbeing. (s 132)	The Director General and persons in charge of mental health facilities are responsible for the storage of information. (ss 132 and 266)	The Director General must remove a registered affected person's information from the affected person register on request by the person or someone with legal authority to act for the person. (s 133)	Disclosures of information held on the register may be disclosed in particular circumstances (s 134), however the Act does not provide for the transfer of information for the purposes of extending the time for which the information can be stored.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Persons in charge of a facility where restraint, including seclusion and medical restraint, is used on a person must make a report of the use of the restraint on the person's record and, if the facility is a community care facility or mental health facility, keep a **restraint register.** (s 266)					
9.	***Mental Health (Secure Facilities) Act 2016*** ***Minister*** *means the Minister for Mental Health.* *This Act applies to an approved mental health facility declared by the Minister under section 7 to be a secure mental health facility. (s 6)*	Who is responsible for health information data is not specified.	The Act authorises approved mental health facilities to keep registers recording patient's contact with others, visitors, mail and searched mail, searches and use of force.	The Act does not specify how long particular records must be kept.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Registers kept under the Act may be kept in any form, including in electronic form.	How long researchers must store data once a study is closed is not specified.
10.	***Territory Records Act 2002*** ***Agency*** *means ACT statutory bodies and public offices.*	The Act does not apply to health records, except for in relation to approved records management programs (ss 16, 17, 19, 21).	An agency that holds personal information must have an approved records management program (s 16)	An agency may only disposed of information in accordance with its approved records management program (s 16(4)).	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Other than requiring that information be managed in accordance with a records management program (s 16), the Act does not specifically require information to be stored in a particular format.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	Note: the Act has limited application to health information records. Health information is otherwise subject to the Health Records Act.	The Act otherwise governs the storage and sharing of information by Agencies.		The director may, in writing, approve for the disposal of an agency's records. (s 19)			
11.	***Health Records (Privacy and Access) Act 1997*** ***Privacy Principles (PPs)*** *under Schedule 1, Health Records (Privacy and Access) Act* ***Record keeper*** *includes any entity with possession or control of a health record.*	A person may only collect health information for inclusion in a health record or in a generally available publication where necessary for or directly related to their official function or activity. (PP 1)	A person must not disclose a health status report to a third party without written consent. (s 7, *Act*) A record keeper must not disclose a health record or health information record without consent, except in limited circumstances including: a) to members of a treating team for the provision of a health service; and b) for the purpose of management, funding or quality of a health service; c) for the purpose of research or statistical compilation or analysis (s 17; PPs 6, 9, and 10)	A record keeper must retain health information until: a) if the consumer is a child when the information is collected, the consumer turns 25; or b) if the consumer is an adult when the information is collected, 7 years after the last service was provided. (PP 4.1(3)) A record keeper and must not destroy health information unless allowed under the Act or another Territory law, or an electronic copy of the record has been generated that will remain readily accessible for reference. (PPs 4.1(2) and 4.1(3))	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Health information may be stored electronically. (PP 4.1(3)) A record keeper must take reasonable steps to protect health information against loss; unauthorised access, use, modification or disclosure; other misuse. (PP 4.1(1)(a)) A record keeper must keep a register of records that have been destroyed or transferred to another entity for at least 7 years after the record was made. (PP 4.2) An entity other than a health service provider must permanently deidentify health information which is no longer needed for any relevant purpose. (PP 4.3(2))	A record keeper must retain health information until: a) if the consumer is a child when the information is collected, the consumer turns 25; or b) if the consumer is an adult when the information is collected, 7 years after the last service was provided. (PP 4.1(3)) A record keeper must not destroy health information unless allowed under the Act or another Territory law, or an electronic copy of the record has been generated that will remain readily accessible for reference. (PPs 4.1(2) and 4.1(3))

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
				Health information may be kept by a health service provider even after its destruction is allowed. (PP 4.3(1))		Where identified health information is disclosed for the purpose of research or statistical analysis or compilation, the record-keeper must: protect against any further disclosure of identifiable information; take reasonable steps to deidentify the information; destroy identifiable information at the earliest possible opportunity; and to ensure that identifiable information is not made publicly available. (PP 10(3))	
12.	***Information Privacy Act 2014*** ***Territory Privacy Principles (TPPs)*** *under Part 3, Division 3.2, Information Privacy Act*	The *TPPs apply to public sector agencies. The Act does not however apply to boards of inquiry, judicial commissions, judicial council, Royal Commissions, and other prescribed agencies (s 24).*	Public sector agencies must have a TPP privacy policy detailing the kinds of personal information it collects and holds, and how it holds it (TPP 1). Collection and storage of information is subject to the Australian Privacy Principles.	Public sector agencies must take reasonable steps to destroy the information once the information is no longer needed for the purpose it was collected, used or disclosed (TPP 11).	Certain disclosures are authorised under the act (s 25). Intended or likely disclosures must be set out in the agency's TPP privacy policy (TPP 1). The Act and TPPs does not specify whether information can be transferred or disclosed for the purposes of extending the time for which it can be stored.	The Act and TPPs do not require information to be held in a particular format, however public sector agencies must detail how the information is held in the agency's TPP privacy policy.	How long researchers must store data once a study is closed is not specified.

Table Seven: Tasmania

Table Seven summarises the Tasmanian legislation which is relevant to the collection and storage of health information. Some, but not all of the legislation summarised in Table Seven is relevant to establishing a national CQR as a quality assurance activity or as a pilot within a research framework. QAAs are subject to special protections that do not otherwise apply to all research conducted for the purposes of maintaining quality and safety or continuous improvements in the health care sector.

CQR as a Quality assurance activity

In Tasmania, protected quality assurance activities engage established under the *Health Administration Act 1982* by a declaration made by the Secretary of the Department of Health under the *Health Administration Act 1982*. Entities that are covered by the *Health Administration Act 1982* may also be eligible to apply for a declaration under the *Health Insurance Act 1973,* however the Commonwealth qualified privilege scheme offers similar protections to the *Health Administration Act 1982* so this additional step may not be necessary.

CQRs within a research framework

An individual or organisation who wishes to establish a CQR as a pilot and/or for development as a national CQR within a research framework requires an identifiable custodian to operate the CQR with approval by a human research ethics committee and acknowledgment by the contributing institutions of their responsibilities as provided in the National Statement. This may require local site specific assessment review by the authorising institution.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
Tasmania							
1.	***Public Health Act 1997***	Director of Public Health is responsible for collecting health information relevant to public health concerns.(ss 42, 56F(4), and 148) The Director of Public Health may establish registers containing health information which may assist in facilitating, protecting, promoting or maintaining public health. (s 143) The Director of Public Health may require a council to keep a register of licences issued by it and in force under this Act. (s 145)	The Director of Public Health collections health information.	How long identified information can be stored is not specified. Identifiable health information may only be disclosed in limited circumstances, including: a) with consent; b) in relation to the provision of health services; c) for the management of notifiable diseases and threats to public health; and d) for the purpose of approved studies or research. (s 147)	The Public Health Act does not specify whether personal information can be transferred to another location for additional storage duration, however health information to be recorded in the Cervical Screening Register may be obtained from or provided to: a) the person; b) a medical practitioner or registered nurse engaged by the person; c) a person in charge of a laboratory engaged by, or on behalf of, the person;	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified. [14]

[14] Research studies funded by the National Health and Medical Research Council must maintain records in accordance with the National Statement – requirement for human research and relevant Records Authority issued by the National Archives of Australia (Archives Act 1983).

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
					d) the person responsible for keeping the National HPV Vaccination Program Register; e) a person responsible for keeping a corresponding register; f) Medicare Australia. (s 137B)		
		The Director of Public Health is responsible for compiling and maintaining a **Cervical Screening Register**. (s 137)	Health information to be recorded in the Cervical Screening Register may be obtained from or provided to: a) the person; b) a medical practitioner or registered nurse engaged by the person; c) a person in charge of a laboratory engaged by, or on behalf of, the person;	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	While the Cervical Screening Register is not required to be kept in a particular format, it may include: a) the person's personal information; b) a number, or other sign, assigned to the person so as to identify the person; c) information as to whether the person is an Aboriginal or Torres Strait Islander, or both;	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			d) the person responsible for keeping the National HPV Vaccination Program Register; e) a person responsible for keeping a corresponding register; f) Medicare Australia. (s 137B) The Director may disclose health information contained in the Cervical Screening Register for the a number of purposes, including: a) to provide general information to persons on the Register about the role and functions of the Register, cervical screening and cervical cancer prevention; b) to provide information for the purposes of the National HPV			d) the person's date of birth; e) the history of the person's cervical cancer tests and the results of those tests; f) the history of the person's cervical cancer treatment; g) HPV vaccination information. (s 137A) Health information may need to be de-identified on request. (s 142) Where individuals elect for their information to be withheld from the register, parties cannot include any relevant health information on the register. (s 140)	

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			Vaccination Program Register or for the purposes of maintaining a corresponding register; c) to provide comparative data from laboratories to encourage consistency of performance; and d) to provide epidemiological data in order for statistical compilation and analysis and program planning purposes.(s 138) Information may have to be de-identified before disclosure. (s 139(c))				
2.	***Guidelines for Notifying Diseases and Food Contaminants*** *issued under the ss 143 and 184 of the Public Health Act 1997*	The superintendent of a laboratory who is aware by way of its functions that a person has evidence of a notifiable disease, is responsible for notifying the Director of Public Health or	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Records must include: a) In relation to cases of specified notifiable diseases, de-identified personal	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Public Health Officer. (Division 1, Part 1) A medical practitioner who is aware or suspects that a person they are attending has a notifiable disease is responsible for notifying the Director of Public Health or Public Health Officer, except where they are aware the relevant party has already been notified. (Division 1, Parts 2(1) and 2(2)) The superintendent of, and the senior health professional responsible for care in, a residential, educational, healthcare, or childcare facility who is aware or suspects that a person residing, attending or working in the facility has gastroenteritis and the case is part of an outbreak is responsible for notifying the Director of Public Health or Public Health Officer				information of the patient; b) in relation to cases of all other notifiable diseases (other than cancer), personal information of the patient; c) In relation to all notifiable diseases (other than cancer), details of the disease, specimen and testing; contact details of the superintendent (where applicable), contact details for the laboratory (where applicable), and contact details of the medical practitioner requesting the test; and d) in relation to gastroenteritis, the contact details of the notifying party; the details of the	

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		except where they are aware the relevant party has already been notified. (Division 1, Parts 3(1) and 3(2))				facility; the details of the person with actual or suspected gastroenteritis; and the basis upon which the notifying party is aware or suspects the case is part of an outbreak. (Division 1, Parts 1(9); 2(6) and 3(4))	
		The Director is responsible for the **Tasmanian Cancer Registry** as a register for the purposes of section 143.of the *Public Health Act 1997*. (Division 2 (b)) The superintendent of a laboratory and the superintendent of a hospital must notify information for the Tasmanian Cancer Registry to Director of the Tasmanian Cancer Registry of its delegate. (Division 2 (c) and (d))	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The notifying party must notify the following information: a) details of the any relevant laboratory or hospital; b) details of the person with evidence of cancer; c) details of the relevant testing; and (d) details of the cancer. (Division 2, Parts 1(3) and 2)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Under section 40 of the *Public Health Act 1997*, the Director requires reporting of **notifiable contaminants**. (Division 3 (a) and (c)). The superintendent of a laboratory who is aware or suspects by way of it functions, or a person who is aware or suspects by reason of information received from a laboratory outside Tasmania, that a notifiable contaminant or a toxin produced by a notifiable contaminant may be present in food is responsible for notifying the Director of Public Health or Public Health Officer, except where carried out for academic or educational purposes and there is no associated threat, or where aware that the relevant party has	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The notifying party must notify the following information: a) the details of the notifying party; b) the name of the laboratory where the test occurred: c) the details of the food; d) the details of the testing. (Division 3, Part 1(13))	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		already been notified. (Division 1, Parts (1), (2), (3), (4) and (5))					
3.	***Guidelines for Notifying Coronavirus Disease 2019 (COVID-19)*** *issued under ss 143 and 184 of the Public Health Act 1997*	The superintendent of a laboratory or medical practitioner who is aware by way of their official functions that a person has evidence of COVID-19 is responsible for notifying the Director of Public Health or a Public Health Officer; except where a medical practitioner is aware that the relevant party has already been notified.(Parts D(1); E(1) and E(2))	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The notifying party must notify the relevant party immediately by telephone or fax and report: a) details of the person with evidence of COVID-19; b) details of the disease and testing; c) contact details of the superintendent; d) details of the laboratory (where applicable); and e) details of the medical practitioner reporting or requesting the test. (Parts D(2); D(3)); E(3) and E(4))	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
4.	***Tasmanian Charter of Health Rights and Responsibilities*** under the *Health Complaints Act 1995*	Health service providers have the right to request information about a consumer's background. (Right 2) Consumers have a right to expect that this information is treated sensitively and kept securely. (Right 3)	Health service providers are permitted to store personal and health information as required for the delivery of health services. (Right 1)	How long identified information can be stored is not specified.	No identifying information about the consumer, their condition or treatment may be disclosed without their consent unless the disclosure is required or authorised by law. (Right 3)	Personal information must be kept securely and must not be publicly accessible. (Right 3)	How long researchers must store data once a study is closed is not specified.
5.	***Mental Health Act 2013*** ***Clinical guidelines and standing orders*** under ss 151 and 152 of the *Act* **Chief Forensic Psychiatrist** means the person appointed by the Governor to that role. **Chief Civil Psychiatrist** means the person appointed by the Governor to that role.	The controlling authority of a secure mental health unit responsible for keeping and reporting appropriate records in respect of each forensic patient in the unit to the Mental Health Tribunal and Chief Forensic Psychiatrist (s 114) The President of the Mental Health Tribunal must give the Minister for Health an annual report on the Tribunal's activities. (s 178)	Where a person makes certain orders, including in relation to admission, discharge, transfer and treatments, particularly of involuntary and forensic patients, they must place a copy of the instrument on the patient's clinical record and notify, as applicable: a) the person who made any initial order; b) the person's treating medical practitioner; c) if the patient is to be, or is likely to	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A person who publishes information for financial or other gain must not publish any information that could identify a person as being or having been a forensic patient or an involuntary patient, except in limited circumstances. (s 133) Matters relevant to the use of urgent circumstances treatment must be documented using Chief Civil Psychiatrist Approved Form 8: Urgent Circumstances Treatment Chief	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			be, assessed in an approved facility, the controlling authority of the facility; d) the Chief Civil Psychiatrist; e) the Mental Health Tribunal; f) Chief Forensic Psychiatrist; g) where the order relates to a transfer, the controlling authority of each hospital; and h) the Secretary (Department of Corrections). (ss 21, 29, 33, 35, 37, 42, 45, 48, 49, 53, 54, 55, 58, 59, 60, 64, 70, 72, 73, 78, 79, 82, 83, 87, 88, 91, 96, 119, 127, 128, 132, 180, 181, 192A, and 224A) A person who publishes information for financial or other gain must not publish any information pertaining to a			Forensic Psychiatrist Approved Form 8: Urgent Circumstances Treatment. (see 5, *Chief Civil Psychiatrist Standing Order 8;* 5, *Chief Forensic Psychiatrist Standing Order 8*) Matters relevant to the use of chemical, mechanical and physical restraint or seclusion must be documented using the appropriate of the Chief Civil Psychiatrist Approved Form 9, the Chief Forensic Psychiatrist Approved Form 9; the Chief Civil Psychiatrist Approved Form 10: Restraint or the Chief Forensic Psychiatrist Approved Form 10. Incidents leading to the application of chemical, mechanical and physical restraint or seclusion must be logged via the incident management systems in place at the relevant time	

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			person's treatment or care as a forensic patient or an involuntary patient except in limited circumstances. (s 133) A person who obtains information about a patient in discharging any responsibilities under the Act must not disclose the information except in limited circumstances including: a) with consent; b) where the disclosure is directly related to the purpose for which the information was obtained and the disclosing party reasonably believes the patient would want or expect the information to be disclosed for that purpose; c) where authorised by the Mental Health Tribunal; d) where necessary in connection			within the approved hospital. (see 14 and 16, *Chief Civil Psychiatrist Standing Order 10*; 17 and 20, *Chief Civil Psychiatrist Standing Order 10A*; 22 and 25, *Chief Civil Psychiatrist Standing Order 9;* 21 and 24 *Chief Forensic Psychiatrist Standing Order 9,* 15 and 18, *Chief Forensic Psychiatrist Standing Order 10;* 17 and 20 ,*Chief Forensic Psychiatrist Standing Order 10A)* The outcome of any capacity assessment conducted should be recorded in Chief Civil Psychiatrist Approved Form 6: Assessment Order or the Mental Health Tribunal Application for Treatment Order Form, Chief Civil Psychiatrist Approved Form 2A: Capacity (Adults), or Chief Civil Psychiatrist Approved Form 2B: Capacity (Children). (see *Chief*	

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			with the administration of the Act. (s 134)			*Civil Psychiatrist and Chief Forensic Psychiatrist Clinical Guideline 2*)	
		The controlling authority of an approved facility is responsible for giving a monthly report on the accommodation and treatment of long-term voluntary inpatients to the Mental Health Tribunal and the Chief Civil Psychiatrist. (s 136)	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The monthly report must be in a form approved by the President of the Mental Health Tribunal or the Chief Civil Psychiatrist and specify at least the name, admission date, and particulars of care and treatment for each relevant patient. (s 136)	How long researchers must store data once a study is closed is not specified.
6.	***Quality and Safety Framework for Tasmania's DHHS Funded Community Sector*** (the Framework) **DHHS** means the Department of Health and Human Services. **CSO** means Community Sector Organisations funded by the DHHS.	The Framework supports DHHS funded CSOs to have systems and processes in place to deliver safe, high quality services to Tasmanian consumers.	The DHHS and CSOs may store personal information collected through the management of reportable consumer related incidents, however storage and management must adhere to the requirements of the *Privacy Information Protection Act 2014* and the *DHHS Personal Information Protection statement*.	Storage and management must adhere to the requirements of the *Privacy Information Protection Act 2014* and the *DHHS Personal Information Protection statement.*	Whether identified health information can be transferred to another location for additional storage duration is not specified.	If the DHHS is required to be notified of a reportable incident, the incident must be notified verbally within 24 hours, or the next working day and by documented report to the DHHS within two working days of the incident occurring. Community sector organisations may utilise the Reportable Incident Form.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		The Framework requires that DHHS funded CSOs have systems and processes in place to record and monitor continuous improvement (CI) activities against recognised standards. Reportable consumer related incidents must be notified to the DHHS. The data custodians are therefore the CSOs and DHHS.					
7.	***Archives Act 1983*** ***Relevant authority*** *means* *a) the Head of a Government department that is established under the State Service Act 2000;* *b) the person directly responsible to the relevant*	The relevant authority is responsible for keeping, preserving and making accessible records in respect of the business of the relevant government department, State authority or local authority for which the relevant authority is responsible. (s 10)	Where a record contains undisclosable information under another enactment, or should not be disclosed for other reasons, including where it would involve the unreasonable disclosure of personal information, a person must not	Where a state record is no longer required to be readily available for the purposes of the Crown or for public use or reference, or has existed as a State record for 25 years, the relevant authority must transfer it to the State Archivist. (s 11)	Whether identified health information can be transferred to another location for additional storage duration is not specified. However, be aware that where a record contains undisclosable information under another enactment, or should not be disclosed for other	Where a relevant authority makes a State record available to the Archives office, it may give written notice: a) that the record contains undisclosable information under another enactment; or b) prohibiting disclosure or	Where a state record is no longer required to be readily available for the purposes of the Crown or for public use or reference, or has existed as a State record for 25 years, the relevant authority must transfer it to the State Archivist. (s 11).[15]

[15] This is the position for all public sector authorities in Tasmania.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	Minister in relation to a department or service of the State that does not form part of the State Service; *c) an incorporated State or local authority; or* *d) the principal executive officer of an unincorporated State or local authority.*		disclose it except in limited circumstances. (s 16)	A person shall not destroy, dispose, damage, alter or transfer a State record, except in limited circumstances. (s 20)	reasons, including where it would involve the unreasonable disclosure of personal information, a person must not disclose it except in limited circumstances. (s 16)	imposing restrictions on disclosure of information which should not be disclosed for other reasons, including where it would involve the unreasonable disclosure of personal information, including of deceased persons. (s 15) Where the State Archivist believes on reasonable grounds that any State records are being kept under control of a relevant authority, they may enter and inspect any relevant places and records and give written advice with respect to the keeping of those records. (s 10)	A person shall not destroy, dispose, damage, alter or transfer a State record, except in limited circumstances. (s 20)

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
8.	***Personal Information and Protection Act 2004*** ***Personal Information Protection Principles* (PIPPs)** **Personal information custodians** include: a) public authorities; or b) any bodies, organisations or persons who have entered into a personal information contract relating to personal information. Note: an exemption to the requirements of the *Act* can be applied for under ss 13 to 15.	A personal information custodian may collect health information in limited circumstances including where: a) necessary for research or statistical compilation or analysis in the public interest relating the individual's racial or ethnic origin for the purpose of government-funded welfare or educational services;	A personal information custodian may direct that access to health information of only be provided to medical practitioners where provision to a person otherwise entitled might be prejudicial to their health or wellbeing. (s 3B) A personal information custodian that is a public authority may disclose an individual's name, residential address, postal address, date of birth and gender to another public sector body where reasonably necessary for the efficient storage and use of that information. (s 12)	A personal information custodian must take reasonable steps to destroy or permanently de-identify health information if it is no longer needed for any purpose, except as provided for in the *Archives Act 1983*. (PIPP 4(2), Sch 1*;* See ss 16 and 17)	A personal information custodian that is a public authority may disclose an individual's name, residential address, postal address, date of birth and gender to another public sector body where reasonably necessary for the efficient storage and use of that information. (s 12)	A personal information custodian must take reasonable steps to protect health information from misuse, loss, unauthorised access, modification or disclosure. (PIPP 4(1), Sch 1*;* See ss 16 and 17) A personal information custodian may only assign a unique identifier to an individual where necessary for the efficient performance of its functions. (PIPP 7(1), Sch 1*;* See ss 16 and 17) A personal information custodian must not adopt as its own unique identifier one that has been assigned by another personal information custodian unless with consent, where necessary or where created under a personal information contract. (PIPP 7(3), Sch 1*;* See ss 16 and 17)	A personal information custodian must take reasonable steps to destroy or permanently de-identify health information if it is no longer needed for any purpose, except as provided for in the *Archives Act 1983*. (PIPP 4(2), Sch 1*;* See ss 16 and 17)

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		b) necessary for research or statistical compilation or analysis in the public interest relevant to public health or safety, or the management, funding or monitoring of a health service. (PIPP 10, Sch 1; See also ss 16 and 17)	A personal information custodian may disclose health information in limited circumstances, including where necessary for research or the compilation or analysis of statistics in the public interest where only de-identified information will be published. (PIPP 2, Sch 1; See ss 16 and 17)		A personal information custodian may only disclose health information to a party outside Tasmania in limited circumstances, including where: the personal information custodian reasonably believes that the recipient is subject to a law, binding scheme or contract that is substantially similar to the personal information protection principles; necessary for the performance of a contract with the personal information custodian; and the personal information custodian has taken reasonable steps to ensure that the health information will not be treated inconsistently with the personal information protection principles. (PIPP 9, Sch 1; See ss 16 and 17)	If a personal information custodian collects health information for research or statistical compilation or analysis in the public interest relevant to public health or safety, or the management, funding or monitoring of a health service it must take reasonable steps to permanently de-identify the information before disclosing it, except in limited circumstances. (PIPP 10 (5) and 10(6), Sch 1; See ss 16 and 17) A personal information custodian must take reasonable steps to destroy or permanently de-identify health information if it is no longer needed for any purpose. (PIPP 4(2), Sch 1; See ss 16 and 17)	

Table Eight: South Australia

Table Eight summarises the South Australian legislation which is relevant to the collection and storage health of information. Some, but not all of the legislation summarised in Table Eight is relevant to establishing a national CQR as a quality assurance activity or as a pilot within a research framework. QAAs are subject to special protections that do not otherwise apply to all research conducted for the purposes of maintaining quality and safety or continuous improvements in the health care sector.

CQR as a Quality assurance activity

In South Australia, protected quality assurance activities are established by declarations made by the Minister for the Department of Health pursuant to the *Health Care Act 2008*. Entities that are covered by the *Health Care Act 2008* may also be eligible to apply for a declaration under the *Health Insurance Act 1973*, however the Commonwealth qualified privilege scheme offers similar protections to the Health Care Act so this additional step may not be necessary.

CQRs within a research framework

An individual or organisation who wishes to establish a CQR as a pilot and/or for development as a national CQR within a research framework requires an identifiable custodian to operate the CQR with approval by a human research ethics committee and acknowledgment by the contributing institutions of their responsibilities as provided in the National Statement. This may require local site specific assessment review by the authorising institution.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
South Australia							
1.	***Public Health Act 2011*** **Minister** means the Minister for the Department of Health. **Chief Public Health Officer** means the medical officer appointed by the Governor, on the recommendation of the Minister, in that role. **Early Childhood Service** means a primary school, a babysitting service, a tuition service, extra-curricular activity providers, out of school care and other child minding organisations.	The Minister, the Chief Public Health Officer, a council or an authorised officer may require a person to furnish such information relating to public health as may be reasonably required for the purposes of this Act. (s 49)	The Minister, the Chief Public Health Officer, a council or an authorised officer may store information that is collected for the purposes of the Public Health Act. (s 49)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified. [16]
		Medical practitioners, pathology services or other prescribed persons are responsible for notifying a diagnosis or death from a **notifiable condition** to the Chief Public Health Office. (s 64) The Chief Public Health Officer must, if there is an immediate threat to public health in the area, as soon as is reasonably	The Minister, the Chief Public Health Officer, a council, an authorised officer, medical practitioners, pathology services and other prescribed persons may store information. (s 64)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A report of a notifiable condition must be made in a manner and form determined by the Chief Public Health Officer; and accompanied by the information required by the Chief Public Health Officer. (s 64)	How long researchers must store data once a study is closed is not specified.

[16] Research studies funded by the National Health and Medical Research Council must maintain records in accordance with the National Statement – requirement for human research and relevant Records Authority issued by the National Archives of Australia (Archives Act 1983).

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		practicable, communicate the contents of the report to the council for the area. (s 64)					
		The parent or guardian of a child that is enrolled or attends an early childhood service must provide immunisation records relating to the child to the provider of the service in accordance with the requirements of the Chief Public Health Officer. (s 96B)	Providers of early childhood services are permitted to store immunisation records. (s 96B) Providers may then be required to provide that information to the Chief Public Health Officer. (s 96C)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.
2.	***Public health emergency Declaration – COVID-19*** under the *Public Health Act 2011* **Chief Executive** means the Chief Executive of the Department of Health.	The Chief Executive must take any necessary action to implement the Public Health Emergency Management Plan and cause such response and recovery operations to be carried out as he or she thinks appropriate.	While the Declaration is in force, the Chief Executive must take any necessary action to implement the Public Health Emergency Management Plan, including collecting, storing and using particular information.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Additional powers may be exercised under the *Emergency Management Act 2004* (SA), including powers to: • make directions to property owners; • direct or prohibit the movement of persons; • direct a person to remain isolated or segregated from other persons, or to take other measures to prevent the transmission of a disease; • direct a person to undergo medical assessment; • direct a person to stop any work or close any premises; and • require information be provided.					

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
3.	***South Australian Public Health (Cervical and Related Cancer Screening) Regulations 2012***	The person in charge of a pathology laboratory must is responsible for providing information to the Chief Public Health Officer. (reg 4)	The person in charge of a pathology laboratory must provide to the Chief Public Health Officer: the patient's details; the details of the medical practitioner who requested the test; the date shown on the pathology request form; the name of the laboratory at which the test was performed; the slide or specimen number assigned to the specimen by the laboratory; the results of the test and the recommendations of the pathologist responsible for the test. (reg 4)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.
4.	***Health Care Act 2008*** **Minister** means the Minister for the Department of Health.	The Minister may, by declaration, authorise particular activities to be **quality improvement** or **authorised research activities.** (s 64)	Quality improvement committees or authorised researchers may store information for the purposes of the authorised activity. (s 64)	How long identified information can be stored is not specified.	Information (including confidential information) may be disclosed for the purposes of an authorised activity without the breach of any law or principle of professional ethics (s 65), however whether identified	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
					health information can be transferred to another location for additional storage duration is not specified.		
5.	***Health Care Regulations 2008*** **Minister** means the Minister for the Department of Health.	Persons in charge of a **birth** must report to the Minister on the details of the birth. (reg 22)	The Minister is responsible for storing pregnancy outcome data and statistics. The person in charge of the birth, the hospital or the infant's mother must report the prescribed information to the Minister. (reg 22)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Information required to be provided by the regulation must be provided in writing (either personally or by post) or in an electronic form acceptable to the Department, so long as a printed copy of the information can be produced if required. (reg 25) The Regulations do not specify how the Minister is to keep the information once received.	How long researchers must store data once a study is closed is not specified.
		The person responsible for the management of a hospital or health service that incorporates a radiotherapy clinic must report events involving **cancers** of a particular type. (reg 27)	The Minister is responsible for storing cancer data and statistics. Registered medical practitioners, persons responsible for the management of the hospital or health service or persons in charge of pathology laboratories are	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The regulations do not specify how the register is to be kept, however report must be made in a form and manner acceptable to the Minister and contain prescribed information. (reg 27)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			responsible for reporting the data. (reg 27)				
		The holder of a licence to operate private health facilities under the *Health Care Act* must keep a register in relation to every patient admitted to hospital. (reg 21)	The holder of a licence to operate private health facilities under the *Health Care Act* must keep a register in relation to every patient admitted to hospital. (reg 21)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The regulations do not specify how the register is to be kept, however the register must contain prescribed details in relation to each patient. (reg 21)	How long researchers must store data once a study is closed is not specified.
6.	***Mental Health Act 2009***	Authorised Officers and Police Officers must keep records relating to the exercise of powers under this Act. (s 58A)	The records are to be kept by authorised officers and police officers. (s 58A)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Act does not specify how the information is to be stored, however is must be in a manner and form approved by the Chief Psychiatrist. (s 58A)	How long researchers must store data once a study is closed is not specified.
7.	***Assisted Reproductive Treatment Act 1988***	The Minister is responsible for keeping a register of donors of human reproductive material used in, or in relation to, assisted reproductive treatment resulting in the birth of a child (the **donor conception register**). (s 15)	The Minister is required to keep the donor conception register, persons authorised and registered to provide assisted reproductive treatment may also keep such information. (s 15)	How long identified information can be stored is not specified, however a donor may apply to have their details removed from the Register. (s 11)	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Act does not specify how the donor conception register is to be kept, however the register must contain, details of the donor, the recipients of assisted reproductive technology and any children born as a result of the assisted reproductive technology. (s 15(2))	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
8.	***Guidance Document for Human Research Biobanks and Associated Data***	The biobank custodian should have the appropriate qualifications and training to carry out their responsibilities. (3.1.14) Biobanks must be established, managed, governed and operated in a manner that protects the privacy and confidentiality of the participants who have contributed biospecimens and their data, and which prevents the inappropriate and unauthorised access to these materials. (3.3(B))	The guidelines require the biobank custodian to develop clear, detailed, publicly available policies, protocols and procedures governing the release of all samples and associated data. If the biobank ceases to exist, the custodian should, where possible, ensure the data / specimen is made available to another biobank. (3.3.4)	How long identified information can be stored is not specified.	The guidelines require the biobank custodian to develop clear, detailed, publicly available policies, protocols and procedures governing the release of all samples and associated data. If the biobank ceases to exist, the custodian should, where possible, ensure the data / specimen is made available to another biobank. The Guideline does not otherwise deal with the transfer of information to another location for additional storage duration. (3.3.4)	The biobank custodian should: develop and implement a combination of mechanisms and robust infrastructure to preserve the privacy and confidentiality of all materials and participant data including: secure storage of samples and data, consent forms, data encryption, coding, separation of information that can readily identify the individual, and/or the use of an independent third party responsible for ensuring identified information is separated from other data, ensure that there are clear, detailed, publicly available policies and protocols guiding the disposal of samples and data in the event of a participant withdrawing consent. (3.3.1.3)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
9.	***SA Health Research Governance Policy***	The Chief Executive of SA Health is responsible for ensuring effective and responsible governance of research across the South Australian public health system. (2) Local Health Network Chief Executive Officers are responsible for: a) ensuring staff are aware of policy requirements; b) appointing a Research Governance Officer and support staff; and c) supporting a culture of responsible research practice. (2)	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Researchers should give appropriate consideration to preventing inappropriate access when storing health information. (3.10.1) Health information data should be handled and stored in accordance with the requirements of all applicable laws and guidelines and any conditions of HREC approval or research governance authorisation. (3.10.1)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		The Chief Executives / Executive Directors / General Managers (or equivalent) of public health organisations are responsible for ensuring all research undertaken at their site complies with policy requirements. (2) Research Governance Officers are responsible for ensuring the overall efficient and effective coordination of research governance applications, procedures and processes. (2, 3)					
10.	***SA Health Research Ethics Policy***	The data custodian has ultimate responsibility to approve or refuse the release of data for a specific research project, independent of the ethical determination made by the reviewing HREC. (3.13)	Who can store health information data is not specified.	The period for which data should be retained should be determined by prevailing standards for the specific type of research, however: a) In general, the minimum period for retention of research data is 5 years from the	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	The period for which data should be retained should be determined by prevailing standards for the specific type of research, however: a) In general, the minimum period for retention of research data is 5 years from the

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
				date of publication. b) For most clinical trials, retaining data for 15 years or more may be necessary. c) For gene therapy, health information must be retained permanently. d) For work with community, cultural or historical value, health information should be retained permanently. (3.16.2)			date of publication. b) For most clinical trials, retaining data for 15 years or more may be necessary. c) For gene therapy, health information must be retained permanently. d) For work with community, cultural or historical value, health information should be retained permanently. (3.16.2)
11.	***SA Health Governance for Safety and Quality in Health Service Organisations Accreditation Resource***	Who is responsible for health information data is not specified.	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Health service organisations should support systemic audit of clinical information and integrate multiple information systems. (1.16)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
						Health service organisations should work towards implementing systems that can provide clinical information into the My Health Record system that use national patient and provider identifiers; and standard national terminologies. (1.17)	
12.	***Code of Fair Information Practice (including the Information Privacy Principles (IPPs))***	The Department of Health and funded service providers may collect health information in limited circumstances including where necessary for research, statistical compilation and analysis, or the management, funding or monitoring of a health service, including for quality assurance purposes. (IPPs 1.1, 10.1, 10.2, 10.3,)	The Department of Health and funded service providers may disclose health information for purposes other than the primary purpose of collection in limited circumstances. (IPPs 2 and 9)	The Department of Health or funded service provider should take reasonable steps to destroy or permanently de-identify personal information if it is no longer needed. (IPP 4.2)	The Department of Health and funded service providers must not transfer personal information about an individual to a third party except for where: a) the sender reasonably believes the recipient of the information is subject to a law, binding scheme or contract which effectively upholds substantially similar principles to the IPPS; b) there is consent;	The Department of Health or funded service provider must take reasonable steps to permanently de-identify the information before disclosure. (IPP 10.4) Identified health information may be used for research approved by a Departmental or Divisional Research and Ethics Committee. (Explanatory notes, IPP 2.1(d)) Organisations must take reasonable steps to protect health information from misuse,	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
					c) The transfer is necessary for the performance of a contract; d) The transfer is for the benefit of the individual; it is impracticable to obtain consent, and the individual would likely consent; or e) The sender has taken reasonable steps to ensure that the information will not be held, used or disclosed by the recipient of the information inconsistently with IPPs. (IPP 2.1)	interference, loss, and unauthorised access, modification or disclosure. (IPP 4.1) Methods for safeguarding security could include: a) Physical measures, for example, locked filing cabinets, clear desk policies and restricted access to offices; b) Organisational measures, such as providing access to information only on a 'need-to-know' basis; c) Training measures; and d) Technological measures. (Explanatory notes, IPP 4.1) The Department of Health and funded service providers may only adopt identifiers assigned by government-related or funded	

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
						entities in limited circumstances. (IPP 7.1)	
13.	***SA Health Record Management Policy Directive***	Who is responsible for health information data is not specified.	Health information must be stored in line with the SA Medical Records Documentation and Data Capture Standards and SA Client Identification Data Standards. (2)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Health information must be stored in line with the SA Medical Records Documentation and Data Capture Standards and SA Client Identification Data Standards. (2) SA Health staff working with a health record must ensure they are maintained in safe, secure and confidential environments in all sites. Records are to be captured into approved record-keeping systems, whether established hard-copy filing systems, electronic systems, or a hybrid of both. (4.4)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
14.	***State Records Act 1997*** ***General Disposal Schedule No. 28: Clinical and Client-Related Records of Public Health Units in South Australia (2014)*** under s 23(2) of the Act GDS 28 applies only to health information held by public agencies operating within one of the five Local Health Networks (LHN): • Central Adelaide LHN • Northern Adelaide LHN • Southern Adelaide LHN • Women's & Children's Health Network	Public Health Units administer, control and own the records covered by GDS 28.[17]	Who can store health information data is not specified.	When and how agencies may dispose of official records depends on the kind of record. Disposal must be done in line with the *Clinical and Client-Related Records of Public Health Units in South Australia Disposal Schedule*. (s 23)	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	When and how agencies may dispose of official records depends on the kind of record. Disposal must be done in line with the *Clinical and Client-Related Records of Public Health Units in South Australia Disposal Schedule*. (s 23)[18]

[17] This is the position for all public sector authorities in South Australia.

[18] This is the position for all public sector authorities in South Australia.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	• Country Health SA LHN.						
15.	***Information Privacy Principles (IPPs) Instruction from the Department of Premier and Cabinet***	Who is responsible for health information data is not specified.	The Department of Health and funded service providers may disclose health information including for purposes other than the primary purpose of collection in limited circumstances. (IPPs 2 and 4(10))	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	An agency should take reasonable steps to ensure that health information in its possession or under its control is securely stored and is not misused. (IPP 4(4))	How long researchers must store data once a study is closed is not specified.
16.	***Information Security Policy Directive***	The Chief Executive of SA Health is accountable for the overall security of SA Health information assets and ensuring information security management is in accordance with this policy directive across SA Health. (2.6) The Information Technology Security Advisor (ITSA) is responsible for providing support and advice to management on security measures required to ensure that information stored, processed or	All access to SA Health information and ICT resources by suppliers and third parties must be assessed, continuously monitored, reviewed and audited for potential security risks and maturity of the security posture. (3.11)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Access to information must be controlled and only authorised users who have a justifiable business reason may access the information. (3.1.3) All SA Health information assets must be identified, have a designated Business Owner and be classified and labelled in accordance to the *Information Asset Classification Policy Directive*. (4.3) Upon disposal approval, physical documents with	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		communicated by SA Health's ICT systems are protected. (2.6) Executives, directors, business owners, senior managers and mangers are responsible for information security in their areas ensuring practices meet the requirements in this policy directive. (2.8) Digital Health SA Security Services are responsible for implementing, managing and controlling information security within SA Health. Administratively, they report to the Chief Digital Health Officer. Functionally, they also report to the Agency Security Executive and Digital Health SA Board. (3.2)				health information must be shredded before disposal or disposed through the appointed confidential paper and destruction servicing company. Media containing electronic health information must be degaussed, wiped, overwritten with meaningless data or disposed through an approved destruction servicing company or process. (3.4) Physical and digital access control measures must be put in place. (3.5, 3.7, 3.8, and 3.9)	

Table Nine: Northern Territory

Table Nine summarises the Northern Territory legislation which is relevant to the collection and storage health of information.

CQR as a Quality assurance activity

The Northern Territory does not currently have legislated qualified privilege arrangements for its health care sector. The *Mental Health and Related Services Act 1998*, quality assurance activities engaged in in relation to mental health services are protected by the Approved Procedures and Quality Assurance Committee Terms of Reference.

Entities that provide Commonwealth funded health services in the Northern Territory are eligible to apply for a declaration under the *Health Insurance Act 1973*.

CQRs within a research framework

An individual or organisation who wishes to establish a CQR as a pilot and/or for development as a national CQR within a research framework requires an identifiable custodian to operate the CQR with approval by a human research ethics committee and acknowledgment by the contributing institutions of their responsibilities as provided in the National Statement. This may require local site specific assessment review by the authorising institution.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
Northern Territory							
1.	***Public and Environmental Health Act 2011*** ***Public and Environmental Health Regulations 2014*** **Chief Health Officer** means the person appointed by the Minister for Health under the Act as the Chief Health Officer.	The Chief Health Officer or its delegate is responsible for collecting and using health information for monitoring, protecting, maintaining or promoting public health. (ss 63, 64, and 69) The Chief Health Officer or its delegate must keep a register of all health information it obtains. (ss 65(1) and 69)	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Chief Health Officer's register of health information may be kept in any form, including in electronic form. (s 65(2))	How long researchers must store data once a study is closed is not specified. [19]
		The Chief Health Officer is responsible for maintaining the NT **Cervical Screening Register**. (reg 7)	The CHO may disclose health information from the Register to: a) corresponding registers including the National HPV Vaccination Program Register;	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Register may be kept in any form the Chief Health Officer thinks appropriate, including electronic formats. (reg 7(2))	How long researchers must store data once a study is closed is not specified.

[19] Research studies funded by the National Health and Medical Research Council must maintain records in accordance with the National Statement – requirement for human research and relevant Records Authority issued by the National Archives of Australia (Archives Act 1983).

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			b) Medicare Australia; c) the NT Cancer Registry; d) a health practitioners and laboratories for limited purposes. (s 9)			Health practitioners must provide health information to the register using the prescribed request form. (reg 11, 12, and 13) Health information must be deidentified on request from the relevant patient. (reg 22) The Register must record personal details of the relevant woman and details of the cervical examination. (Sch 2, *Regulation*)	
		The Chief Health Officer is responsible for maintaining a **register of perinatal information**. (reg 58)	The Chief Health Officer may provide information recorded in the collection to: a) the Australian Institute of Health and Welfare; b) the Registrar of Births, Deaths and Marriages; c) corresponding registers; d) other persons authorised by the	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Register may be kept in any form the Chief Health Officer think appropriate, including electronic formats. (reg 58) Information about the following must be given to the register: a) births and still-births; b) the diagnosis of a structural or functional abnormality in a child aged up to	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			Chief Health Officer. (reg 67)			12 months that was present during pregnancy; and c) notifiable deaths of children and women. (regs 60, 61, 62, 63, 64, and 65)	
2.	***Health Services Act 2014*** ***Central Australia Health Service 2019-20 Service Delivery Agreement and*** ***Top End Health Service 2019-20 Service Delivery Agreement* (SDAs)** under s 37 of the Act **COO** means the Chief Operating Officer of the relevant Health Service **CEO** means the Chief Executive Officer of the Department of Health	The CEO is responsible for: a) setting the performance standards and monitoring the performance for the provision of health services; b) collating and reporting data on the performance of the Public Health System; and c) taking action to examine or improve the performance of a Service. (s 14)	The COO must report to the CEO quarterly on the performance of the Service. (s 46) The Department of Health must provide annual reports on the performance of each Health Service to the Minister of Health. (s 47)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Health Service will provide data in the form and manner as established in front-line clinical settings and in agreements. (7.3, *SDAs*)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		The COO is responsible for, amongst other things, implementing record keeping and information management systems for the Service. (s 32) Health Services must provide the following data: a) as required to deliver and manage clinical care and services; b) as required to report to national bodies; c) as required under relevant legislation; d) as required to facilitate reporting against key performance indicators; e) as required to determine activity based funding and block funding;					

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		f) as required to monitor implementation of NT Health policies and whole of Government plans; and g) as requested by the CEO. (7.3, *SDAs*)					
3.	***Mental Health and Related Services Act 1998***	A person-in-charge of an approved treatment facility must notify the Chief Executive Officer of the Department of Health, the Mental Health Tribunal of the length of time a voluntary patient has been admitted, where they have been admitted for a continuous period of 6 months. (s 28) Where a person is admitted as an involuntary patient under a recommendation allowing the person to be detained for longer than 72 hours, a practitioner must notify the Mental	A person who obtains information carrying out functions under the Act must not record, use or disclose the information except as allowed under the Act. (ss 117 and 139)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Health Tribunal and the principal community visitor. (ss 41(1)(e), 43(1)(e)) A practitioner must notify the appropriate parties of the principal community visitor appointed under the Act when certain orders are made. (ss 47 and 50A) The Approved Procedures and Quality Assurance Committee is responsible for reviewing approved procedures and forms and assessing the quality of mental health services. (s 145(2))					
4.	***Approved Procedures and Quality Assurance Committee Terms of Reference***	The Approved Procedures and Quality Assurance Committee is responsible for reviewing approved procedures and forms and assessing the quality of mental health services. (s 145(2), *Mental Health*	A person who obtains information carrying out the functions of a committee must not record, use or disclose the information except as allowed under the Act. (Appendix A))	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Health information in committee reports must be de-identified except with consent. (Appendix A)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		and Related Services Act 1998)					
5.	***Northern Territory Health Data Release Guideline***	The Northern Territory of Australia is the legal owner of all data collected by, within and for NT Health. The Chief Executive of the Department of Health has primary responsibility (on behalf of the Territory) for the security, management, use and disclosure of the data. (8)	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Patient/client names and addresses are not stored within the Department of Health's data collections and are only available for the purpose of enabling data linkage. (5.2.1) The patient/client's medical record number will only be provided to external parties where there is no alternative to its provision.(5.2.1) Health provider local identifiers will not be provided outside NT Health. (5.2.2) Data that identifies an organisation or Aboriginal community is only disclosable with consent. (5.2.2 and 5.2.3) Data will be provided in an agreed format, generally as a delimited or fixed width text file or in MS Excel, depending on file size. All files	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
						transmitted externally to the NTG network or email will be encrypted and password protected, with the password provided separately to the file. (5.8)	
6.	***Health and Community Services Complaints Act 1998***	The Commissioner may obtain documents in relation to complaints and use that information in dealing with the complaints. (s 55)	Who can store health information data is not specified.	Information may only be stored for the period that is necessary for the purposes of the investigation to which it relates. (s 60)	If a document is produced or seized in accordance with this Part, or otherwise obtained under this Act, the Commissioner may: a) take possession of the document and make copies of or take extracts from the document; or b) retain the document for the period that is necessary for the purposes of the investigation to which it relates. (s 60)	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.
7.	***Code of Health and Community Rights and Responsibilities*** The Code applies to health care	Providers are responsible for upholding their duties under the Code.	Users have a right to information about their health, care and treatment. However, they do not have an automatic right of access to their care	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage	Formats for storing health information are not specified.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	providers who store information related to users of health care services.		or treatment records. (Principle 4) Providers may prevent users from accessing their records in certain circumstances. (Principle 4) Providers have a responsibility to protect the confidentiality and privacy of users by: ensuring that the user's information held by them is not made available to a third party unless: the user gives written authorisation for the release; subject to subpoena or pursuant to legislation; or it is essential to the provision of good care and treatment and the provider obtains the user's consent. This may take the form of consent to share information between a treating team. (Principle 4)		duration is not specified.		

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			Providers must have policies and procedures in place, including policies relating to the storage of information, and ensuring all staff are aware of these. (Principle 4)				
8.	***Cancer (Registration) Act 2009*** ***Cancer (Registration) Regulations 2010*** **Minister** means the Minister for Health. **Registrar** means the person appointed by the Minister to keep the Register.	The Minister is responsible for appointing a registrar to keep a register of cancer diagnoses. (ss 6 and 7) Persons in charge of pathology services are responsible for reporting positive test samples to the Registrar within 7 days of receiving the test results. (s 8) Persons in charge of hospitals are responsible for reporting diagnoses and deaths within 7 days. (s 9) If the registration of a person's death under the *Births, Deaths and Marriages Registration Act 1996* shows cancer as a cause of death, the	The Register is kept by the Registrar. (ss 6 and 7)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Regulations set out the prescribed details to be included on the register. (reg 3) The Act and Regulations do not otherwise specify how the Register is to be kept.	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		Registrar of Births, Deaths and Marriages is responsible for reporting give to the Registrar the details contained in the registration. (s 11)					
9.	***Medicines, Poisons and Therapeutic Goods Act 2012***	The pharmacist-in-charge of a pharmacy; relevant health staff; and any holder of a relevant authorisation; must keep registers in relation to prescribed substance they hold. (ss 44, 46, 48, 50, 51, 52, 55, and 58)	Who can store health information data is not specified.	Registers must be kept for at least 2 years after the day on which the last entry is made in the register. (s 61)	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Registers must record details of any transaction, details of the recipient, and details of the relevant medicine or regulated substance. (ss 45, 47, 49, 53, 54, 56, 57, and 59.) Registers must be legible and in English. (s 60)	How long researchers must store data once a study is closed is not specified.
10.	***Information Act 2003*** The Act applies to personal information held, collected or handled by a public sector organisation.	Public sector organisations are to make government information available to the public and must assist the public to ensure that personal information is accurate, complete and up to date. (s 10)	Public sector organisations are required to publish information about the organisation in publicly accessible formats and may publish government information when it is in the public interest to do so. (s 11)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A public sector organisation must keep records in a form in which they are capable of being read and reproduced, which may be an electronic form. (s 136)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
11.	***Information Privacy Principles***	A public sector organisation must not collect personal information unless the information is necessary for one or more of its functions or activities. (IPP 1.1)	A public sector organisation must take reasonable steps to ensure that the personal information it collects, uses or discloses is accurate, complete and up to date. (IPP 3)	How long identified information can be stored is not specified.	Disclosures of personal information are permitted only in limited circumstances. (IPP 2) Whether identified health information can be transferred to another location for additional storage duration is not specified.	A public sector organisation must give an individual entering transactions with the organisation the option of not identifying himself or herself unless it is required by law or it is not practicable that the individual is not identified. (IPP 8) The IPPs do not otherwise specify how information is to be stored.	How long researchers must store data once a study is closed is not specified.

Table Ten: Western Australia

Table Ten summarises the Western Australian legislation which is relevant to the collection and storage health of information. Some, but not all of the legislation summarised in Table Ten is relevant to establishing a national CQR as a quality assurance activity or as a pilot within a research framework. QAAs are subject to special protections that do not otherwise apply to all research conducted for the purposes of maintaining quality and safety or continuous improvements in the health care sector.

CQR as a Quality assurance activity

In Western Australia, protected quality assurance activities are established by declaration of the Health Minister under the *Health Services (Quality Improvement) Act 1994*. Entities that are covered by the *Health Services (Quality Improvement) Act 1994* may also be eligible to apply for a declaration under the *Health Insurance Act 1973*, however the Commonwealth qualified privilege scheme offers similar protections to the *Health Services (Quality Improvement) Act 1994* so this additional step may not be necessary.

CQRs within a research framework

An individual or organisation who wishes to establish a CQR as a pilot and/or for development as a national CQR within a research framework requires an identifiable custodian to operate the CQR with approval by a human research ethics committee and acknowledgment by the contributing institutions of their responsibilities as provided in the National Statement. This may require local site specific assessment review by the authorising institution.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
Western Australia							
1.	***Public Health Act 2016*** ***Public Health Regulations 2017*** **Chief Health Officer** means the person appointed by the Minister for Health in that role.	A medical practitioner, nurse practitioner, or pathologist who believes a patient has, may have, or has had a notifiable condition is responsible for notifying the Chief Health Officer. (ss 94 and 95)	Health information may be disclosed to or collected from public health officials, enforcement agencies, a public authority; a Commonwealth, State or Territory department or agency, a body, corporate or unincorporate, continued for a public purpose under a Commonwealth, State or Territory law, and the World Health Organisation. (s 299(4)) Health information may otherwise be disclosed in limited circumstances. (s 298)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A notification of the presence of a notifiable disease must include personal information of the relevant person, details of the disease or condition, details of any treatment, and tracing details. (reg 6)	How long researchers must store data once a study is closed is not specified. [20]

[20] Research studies funded by the National Health and Medical Research Council must maintain records in accordance with the National Statement – requirement for human research and relevant Records Authority issued by the National Archives of Australia (Archives Act 1983).

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
2.	***Health (Miscellaneous Provisions) Act 1911*** ***Health (Section 335 (5) (D) Abortion Notice) Regulations 1998*** ***Health (Notifications by Midwives) Regulations 1994*** ***Notification of Stillbirth and Neo-Natal Death Regulations 1955*** **Chief Health Officer** means the person appointed by the Minister for Health in that role.	The Chief Health Officer is responsible for all Anaesthetic Mortality Committee, Maternal Mortality Committee and Perinatal and Infant Mortality records, reports, statements, memoranda and other documents. (ss 340LA(2), 340ALA(2), and 340BLA(2)) Midwives and medical practitioners are responsible for reporting all births, stillbirths, abortions, and deaths of women as the result of complications arising from or following pregnancy or childbirth to the Chief Health Officer. (ss 335 and 336)	A Maternal Mortality Committee may consider health information in the course of its functions. (s 340K) A Perinatal and Infant Mortality Committee may consider health information in the course of its functions. (s 340AB) An Anaesthetic Mortality Committee may consider health information in the course of its functions. (s 340BK) Information disclosed for research purposes must not be disclosed except as strictly essential for research purposes. (ss 340M, 340AM, and 340BM)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Notifications of abortion must be deidentified and in the prescribed form. (reg 335(5); Sch 1, *Abortion Notice Regulations*) Notifications by midwives must be in the prescribed form. (regs 3 and 4, and Sch 1, *Notifications by Midwives Regulations*) A report of an investigation must be in the form of a connected medical case history and deidentified. (ss 336A and 336B) Maternal Mortality and Perinatal and Infant Mortality health information is to be kept in safe custody. (ss 340LA(2), 340ALA(2), and 340BLA(2)) Results may need to be deidentified before being published or made available. (s 340AL)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		A medical practitioner who certifies the cause of death for any stillborn children of more than 20 weeks gestation and children under one year old must report that fact to the Chief Health Officer who must cause an investigation report to be produced. (s 336A) Any person who administers anaesthetic to a person who dies under or as a result of complications arising from that anaesthetic is responsible for reporting the death to the Chief Health Officer. (s 336B)				Medical practitioners must notify the Chief Health Officer of any stillbirth or death of neonate using the prescribed form. (reg 2; and Sch 1; *Stillbirth and Neo-Natal Death Regulations*)	
3.	***Health (Rheumatic Heart Disease Register of Western Australia) Regulations 2015*** **Chief Health Officer** means the person appointed by the Minister for Health in that role.	The Chief Health Officer maintains the **Rheumatic Heart Disease Register** of Western Australia. (reg 13) The following must notify the Chief Health Officer about a person with acute rheumatic fever or rheumatic heart disease:	A person must not disclose information they hold due to their functions in relation to the register except in limited circumstances, including: a) for use in approved research;	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The register is to be kept in a manner and form determined by the Chief Health Officer. (reg 13(5)) A notifying person must give the Chief Health Officer the personal details of the patient, information about the diagnosis, copies of	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		a) the chief executive officer of any relevant hospital or medical centre; b) any medical practitioner or nurse practitioner who diagnoses or treats a patient with acute rheumatic fever or rheumatic heart disease, unless they reasonably believe the Chief Health Officer has been notified. (reg 5)	b) to the Australian Institute of Health and Welfare for limited purposes; and c) for the purpose of inclusion in a national data collection. (regs 13(4),14, and 15)			each medical test and specialist report related to the relevant condition. (regs 9 and 11) Health information may have to be de-identified upon request of the relevant person. (reg 17)	
4.	***Health (Western Australian Cancer Register) Regulations 2011*** **Chief Health Officer** means the person appointed by the Minister for Health in that role.	The Chief Health Officer maintains the Western Australian **Cancer Register**. (reg 10) Any examining specialist, radiation oncologist, ophthalmologist, who becomes aware that a specimen indicates the existence of cancer, and any chief executive of a hospital where a patient is treated for cancer must report that fact to	A person must not disclose information they hold due to their functions in relation to the register except in limited circumstances, including: a) for use in approved research; and b) to the Australian Institute of Health and Welfare for limited purposes	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The register is to be kept in a manner and form determined by the Chief Health Officer. (reg 10(5)) A notifying person must give the Chief Health Officer the personal details of the patient, and information about the diagnosis and any treatment. (Sch 1)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		the Chief Health Officer, except in limited circumstances. (regs 5, 6, 7, and 8)	(regs 10(4),11, and 12)				
5.	***Health (Cervical Screening Register) Regulations 1991*** **Chief Health Officer** means the person appointed by the Minister for Health in that role.	The Chief Health Officer maintains the **Cervical Screening Register**. (reg 5(1))	A person must not disclose information they hold due to their functions in relation to the register except in limited circumstances, including for use in approved research and data collection programs. (regs 6, and 7)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Register contains a compilation of results, or copies of results, of cervical cancer tests. (reg 5(2)) Health information may have to be de-identified before use. (regs 6(2), and 10)	How long researchers must store data once a study is closed is not specified.
6.	***Health (Western Australian Register of Developmental Anomalies) Regulations 2010*** **Chief Health Officer** means the person appointed by the Minister for Health in that role.	The Chief Health Officer maintains the Western Australian **Register of Developmental Anomalies**. (reg 8) If a developmental anomaly is diagnosed the Chief Health Officer of the hospital where the diagnosis was made, or where no hospital is involved, the medical practitioner who makes the diagnosis or is responsible for the care of the patient,	A person must not disclose information they hold due to their functions in relation to the register except in limited circumstances, including: a) for use in approved research; b) to the Australian Institute of Health and Welfare for limited purposes; and c) for the purpose of inclusion in a	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The register is to be kept in a manner and form determined by the Chief Health Officer. (reg 8(5)) Health information may have to be de-identified upon request of the relevant person. (reg 12)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		must, notify the Chief Health Officer. (reg 6)	national data collection. (regs 8(4),9, and 10)				
7.	***Health (Notification of Stimulant Induced Psychosis) Regulations 2010*** **Chief Health Officer** means the person appointed by the Minister for Health in that role.	The Chief Health Officer maintains the **Stimulant Induced Psychosis Register**. (reg 7) A psychiatrist who diagnoses a patient with stimulant induced psychosis is responsible for notifying the Chief Executive Officer of the Department of Health of that fact. (reg 5(1))	A person must not disclose identifiable health information except in limited circumstances. (reg 8)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A notifying person must give the Chief Health Officer the personal details of the patient, and information about the diagnosis. (reg 5(6)) The register is to be kept in a manner and form determined by the Chief Health Officer. (reg 7(3))	How long researchers must store data once a study is closed is not specified.
8.	***Health (Notification of Lead Poisoning) Regulations 1985*** **Chief Health Officer** means the person appointed by the Minister for Health in that role.	The Chief Health Officer is responsible for maintaining the Western Australian **Lead Poisoning Register.** (reg 7(1)) Any medical practitioner who attends a person who has had lead poisoning, or pathologist responsible for the day-to-day running of a laboratory where lead poisoning is diagnosed, must notify	A person must not disclose health information except in limited circumstances. (regs 8 and 9)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Health information may have to be de-identified upon request of the relevant person. (reg 11) The register is to be kept in a manner and form determined by the Chief Health Officer. (reg 7(5))	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		the Chief Health Officer. (regs 5 and 6)					
9.	***Health Services Act 2016*** **CEO** means the Chief Executive Officer of the Department of Health	The CEO functions, amongst other things, to receive and validate performance data and other data provided by service providers. (s 20) The CEO is responsible for maintaining systems for the collection, receipt, storage and disclosure of, and access to, health information. (s 214(1)) Information in a health information management system is held on behalf of the State. (s 14(3))	Health information may be disclosed in limited circumstances, including: a) the management of health service providers; b) the planning for, provision, monitoring and evaluation of public health services; and c) health related research. (ss 216, 217, 218, 219, and 220)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Health information may be held in a health information management system. (s 215)	How long researchers must store data once a study is closed is not specified.
10.	***WA Health Data Collection Policy*** under ss 26 and 27 of the *Health Services Act 2016* This policy applies to all data collections held by or within WA Health.	All data collections within scope must have a Data Steward and Data Custodian assigned. Data Stewards are responsible for setting the overall strategic direction of data collections and authorising the access, use and disclosure of	Who can store health information data is not specified.	How long identified information can be stored is not specified.	When third parties are collecting data on behalf of WA Health, a contract between WA Health and the third party must be in the prescribed form. (3.9)	A data dictionary must be developed to describe the content, format and structure of the collection and the relationships between elements. (3.6) Data collections must be protected from unauthorised access, use or disclosure. (3.8)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		information from data collections. Data Custodians have delegated responsibility for the day-to-day management of the data collection. (3.2)					
11.	***WA Health Information Use and Disclosure Policy 2017*** under ss 26 and 27 of the *Health Services Act 2016* This policy applies to all information generated, collected, accessed, used, managed, stored and disclosed by the WA health system.	Who is responsible for health information data is not specified.	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Health Service Providers are required to take all reasonable steps, to ensure information is protected from misuse, interference, loss, unauthorised access or modification. (3.6)	How long researchers must store data once a study is closed is not specified.
12.	***WA Health Information Storage and Disposal Policy*** under ss 26 and 27 of the *Health Services Act 2016*	WA Health must retain ownership of all of its health information. (2.5)	Who can store health information data is not specified.	The WA Health Recordkeeping Plan details the retention period for all types of records of health and other functional information. (2.6) A register of records destroyed must be maintained and include details of	Semi-active or inactive hard copy records may be transferred to secondary storage facilities where the relevant contracts are in the approved form. (2.1) Current WA Health Recordkeeping	Physical records should be stored to protect the data from unauthorised access and theft, and from any physical damage or deterioration. (2.1) Electronic records should be stored in line with the WA Health Long Term	The WA Health Recordkeeping Plan details the retention period for all types of records of health and other functional information. 2.6) A register of records destroyed must be maintained and include details of

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
				each individual record destroyed, as well as reference to the relevant Retention and Disposal Authority. (2.8)	Plans do not allow for the use of an external data storage provider. (2.5)	Management of Electronic Records Policy (OP 1872/04) to ensure they maintain functionality and are migrated forward when hardware and software changes. (2.2) The *Information & Communications Technology (ICT) Physical & Environmental Security Policy* (OD 0506/14) should be applied to ICT facilities to safeguard equipment and information from unauthorised intrusion and damage. Only WA Health registered portable devices should be used for storing or transporting health information and data must be encrypted and transferred to primary storage as soon as practicable. (2.4)	each individual record destroyed, as well as reference to the relevant Retention and Disposal Authority. (2.8)

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
13.	***WA Health Digitisation and Disposal of Patient Records Policy*** under ss 26 and 27 of the *Health Services Act 2016*	Who is responsible for health information data is not specified.	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Digitised patient records must be captured in accordance with best practice technical standards and WA Health must implement scanning technology that supports the preservation, retrieval and use of the DPR. WA Health must retain metadata of all digitised records even after disposal of the record itself in line with the *WA Health Information Storage and Disposal Policy*. (3.3; see also *WA Health Metadata Documentation Policy)*	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
14.	***WA Health Information Security Policy*** under ss 26 and 27 of the *Health Services Act 2016*	Who is responsible for health information data is not specified.	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Where third party organisations are contracted to provide ICT services for WA Health, contracts must contain appropriate measures to ensure the protection of health information and infrastructure and adhere to system wide policy and processes. (3.2.16)	Information security must alight with the following Australian Standards for Information Security: a) AS/ISO 27002: 2015, Information Technology – Security techniques – Code of practice for information security management; and b) AS/ISO 27799: 2011, Information security management in health using ISO/IEC 27002. (1) Data must be protected against unauthorised alteration or destruction. (3.1) Digital and physical access controls must be implemented. (3.2)	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
15.	***WA Health Data Quality Policy*** under ss 26 and 27 of the *Health Services Act 2016*	Data custodians are responsible for: a) evaluating the quality of data for internal use; b) advising primary and secondary users of any strengths and limitations of the data; c) informing data quality statements that accompany a data submission or for reporting purposes; and d) identifying and implementing strategies for data quality improvement. (3)	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A standardised approach should be used for uniquely identifying health systems, healthcare providers and individuals. (3 (Principle 4)) Key resources and supporting documentation should be readily available. (3 (Principle 5), *Policy*) A standardised approach should be used for reporting and maintaining metadata about data collections. (3 (Principle 5))	How long researchers must store data once a study is closed is not specified.
16.	***Data Stewardship and Custodianship Policy*** under ss 26 and 27 of the *Health Services Act 2016* Data that is: a) exclusively owned by external organisations or agencies;	The State of WA is the legal owner of all data collected by, within and for WA Health. The Director General of the Department of Health is the delegated owner of this data and is responsible for its security, management and legitimate use and disclosure. (4)	Who can store health information data is not specified.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Policy does not specify a format for storing information.	Data pertaining to research is the responsibility of the researcher and must be managed in accordance with the conditions of data release, as well as ethics and site approval requirements. (2)

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	b) collected by WA Health staff for the primary purpose of research; or c) released outside of WA Health for research is excluded from the scope of this policy.	Where stewardship responsibilities for data collections are not assigned by statute, the Director General of the Department of Health delegates these responsibilities. (4) Data custodianship responsibilities for data collections must be assigned to a position rather than a named person. (6)					
17.	***Health Services (Quality Improvement) Act 1994*** ***Health Services (Quality Improvement) Regulations 1995***	Quality improvement committees function to: a) assess and evaluate the quality of health services, including the review of clinical practices; b) report on and make recommendations regarding health services; and c) monitor of the implementation of those recommendations. (s 7) The Act and Regulations also apply	Each Committee must provide the Minister of Health with annual reports. (reg 10)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A Committee is to cause any reports furnished to, information made available to, or documents used in the preparation of reports by, the Committee to be kept in safe custody. (reg 7) Annual reports should detail: a) the reports made available to the public; b) the extent to which the Committee's activities have been facilitated	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
		to the Maternal Mortality Committee, the Perinatal and Infant Mortality Committee, and Anaesthetic Mortality Committee constituted under the *Health (Miscellaneous Provisions) Act 1911*. (s 14)				by the provision of the immunities and protections of the Act; and c) the extent to which restricting disclosure of information is in the public interest. (reg 10)	
18.	***Private Hospitals and Health Services Act 1927*** Alternatively known as *Hospitals and Health Services Act 1927, Hospitals Act 1927* **CEO** means the Chief Executive Officer of the Department of Health.	The CEO may direct a private hospital service provider to give to the CEO the specified information (s 26S).	Private hospitals necessarily hold information, which may then be provided to the CEO.	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	Information is not required to be given in a particular form, however the direction may specify the information by reference to a class of information and may specify the form in which it is to be given (s 26S(4)).	How long researchers must store data once a study is closed is not specified.
19.	***Human Reproductive Technology Act 1991*** ***Human Reproductive Technology Regulations 1993*** **Licensee** means a person authorised or permitted under	Licensees must keep proper records of those who participate in reproductive technologies and eggs and gametes kept or used. (s 44) Licensees must all keep records or of all research relating to reproductive	Licensees must retain the relevant information, however the CEO may request any information in respect of reproductive technology and the CEO reasonably requires (s 44).	How long identified information can be stored is not specified.	The Act does do not specify whether identified information provided in accordance with a request by the CEO can be transferred to another location for additional storage duration, however no information shall be	Information must be kept and retained in a proper record, in such a manner as to keep secure the confidential nature of the information contained in that record, in a place in the State approved by the CEO for the	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
	the act to carry on, supervise or manage a reproductive technology practice or specified activities.	technology conducted, authorised or facilitated by or on behalf of that licensee. (s 44)	The CEO keeps registers containing current information supplied by, or otherwise obtained from, licensees in respect of — a) the identity of participants; and b) the outcome of procedures, showing the genetic origin of the human gametes, human egg undergoing fertilisation or human embryo used; and c) the identity of children born as a result of an artificial fertilisation procedure, including the identity of each biological parent; and d) such relevant demographic and clinical information. (reg 4) Licensees must provide annual		removed from any such record before the expiry of such period as may be specified in the Rules or by directions for information of that kind (s 44).	purpose, for the prescribed number of years after the date on which it was compiled (s 44).	

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
			reports to the CEO. (s 47)				
20.	***Medicines and Poisons Act 2014* (WA)** **CEO** means the chief executive officer of the Department of Health.	The CEO maintains the drugs of addiction register which records: a) information relating to the supply and prescription of drugs of addiction; and b) drug dependent persons and oversupplied persons. (s 88)	A health professional who reasonably believes a patient is drug dependent, oversupplied must notify the CEO. (ss 80 and 84) The CEO may decide to record a person as drug dependent or oversupplied on the drugs of addiction record person if the CEO reasonably believes it to be the case. (ss 81 and 85)	How long identified information can be stored is not specified.	Whether identified health information can be transferred to another location for additional storage duration is not specified.	The Policy does not specify a format for storing information.	How long researchers must store data once a study is closed is not specified.
21.	***Medicines and Poisons Regulations 2016***	Any pharmacist who supplies certain restricted medicines must keep a record of the fact. (regs 142 and 143) A authorised person who manufactures, receives, stores, supplies, administers or transports Schedule 8 or Schedule 9 poisons must keep a register. (reg 144(2))	Who can store health information data is not specified.	Records of supply of restricted medicines must be kept for at least 2 years, or in the case of a schedule 8 poison, 5 years, from the date on which the medicine is supplied. (regs 142(3)(a), and 143(2)) Information on a register must be kept for at least 5 years from the date the information is	Whether identified health information can be transferred to another location for additional storage duration is not specified.	A register kept for the purposes of regulation must be kept in a manner and form approved by the CEO. (reg 146) An electronic system may only be used for keeping a register where: a) entries in the register cannot be deleted or changed; b) entries in the register cannot be made by	How long researchers must store data once a study is closed is not specified.

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
				recorded. (regs 144(7))		unauthorised persons; c) information is capable of being reproduced on paper in a written form; d) the system identifier of a person is automatically recorded in the register when the person makes an entry; and e) other electronic access control measures are in place. (regs 146(2) and 147) Each entry in a register must be signed by the person who is responsible for keeping the register. (reg 144(6))	

	Legislation	Role and function of the custodian	Who can store health information data?	How long can identified health information be stored?	Can identified health information be transferred to another location for additional storage duration?	What formats are used to store health information?	How long must researchers store data once a study is closed?
22.	***State Records Act 2000 (WA)***	The Chief Executive Officer of the Department of Health is responsible for ensuring that the Department of Health complies with the Act. (s 10)	Health information must be dealt with in accordance with the WA Health Record Keeping Plan.[21] (Part 3)	Health information must be dealt with in accordance with the WA Health Record Keeping Plan. (Part 3)	State organisations may enter into an arrangement with a third party for them to perform any aspect of record keeping for the organisation. Where this occurs, the organisation must notify the Director of State Records. (s 33)	Health information must be dealt with in accordance with the WA Health Record Keeping Plan. (Part 3)	Health information must be dealt with in accordance with the WA Health Record Keeping Plan. [22] (Part 3)

[21] The WA Health Record Keeping plan (ss 11 and 12 of the Act) appears to only be available via the WA Health intranet.

[22] This is the case for all public entities in Western Australia.

Annexure A

Quality Assurance Activities declared under the *Health Insurance Act 1973* (Cth)

1. Australian Otolaryngology Head and Neck Quality Assurance Network, Health Insurance (Quality Assurance Activity) Declaration 2018 (No. 1), 5 March 2018
2. Tonsil, Grommet and Nasal Septum Surgery Registry, Health Insurance (Quality Assurance Activity) Declaration 2018 (No. 2), 5th March 2018
3. The Australian and New Zealand Tripartite Anaesthetic Data Committee (ANZTADC) Incident Recording and Reporting Program – webAIRS, Health Insurance (Quality Assurance Activity) Declaration 2018 (No. 3), 16 April 2018.
4. The Australian Corneal Graft Registry (ACGR), Health Insurance (Quality Assurance Activity) Declaration 2018 (No.4), 4 December 2018.
5. Emergency Medicine Events Register (EMER), Health Insurance (Quality Assurance Activity) Declaration 2018 (No.5), 10 December 2018.
6. Australian and New Zealand Audit of Surgical Mortality (ANZASM) (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 1/2017)
7. Perinatal Mortality and Morbidity Audits: learning from adverse events to improve care (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 2/2017)
8. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 3/2017)
9. Practice Visits: A Peer Review Activity for Specialists Obstetricians and Gynaecologists in Australia (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 5/2017)
10. ANZCA Continuing Professional Development (CPD) Program – Practice Evaluation (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 6/2017)
11. RACS Morbidity Audit and Logbook Tool (MALT): Self-reflection and Supervisor/Assessor Feedback (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 1/2016)
12. RACS Morbidity Audit and Logbook Tool (MALT): Audit of Surgical Care (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 2/2016)
13. The Royal Australasian College of Surgeons (RACS) (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 3/2016)
14. BiNational Colorectal Cancer Audit (BCCA) (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 4/2016)
15. QPA: Accreditation for entry into or maintenance of Practice Incentive Program (PIP) (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 5/2016)
16. Australian and New Zealand Gastric and Oesophageal Surgical Association (ANZGOSA) Audit (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 6/2016)

17. Australian and New Zealand Audits of Surgical Mortality (ANZASM) (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 7/2016)
18. The Australian and New Zealand Intensive Care Society (ANZICS) and Centre for Outcome and Resource Evaluation (CORE) Intensive Care Registries (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 8/2016)
19. Australasian Vascular Audit (AVA) (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 9/2016)
20. Australian Vigilance and Surveillance System for Organ Donation and Transplantation (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 10/2016)
21. Professional Qualities Reflection (PQR) of the Royal Australasian College of Physicians (RACP) (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 11/2016)
22. MyCPD of the Royal Australasian College of Physicians (RACP) (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 12/2016)
23. Royal Australian and New Zealand College of Radiologists (RANZCR) Quality and Accreditation Program (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 13/2016)
24. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 14/2016
25. Practice Visit Program (Declaration of Quality Assurance Activities under section 124X of the Health Insurance Act 1973 – QAA 1/2015)
26. Australian and New Zealand Society of Cardiac and Thoracic Surgeons' Cardiac Surgery Monitoring Program (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 2/2015)
27. CareTrack Kids – The appropriateness of healthcare delivered to Australian children (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 3/2015)
28. Improvement of surgeons' operative outcomes and better health outcomes for patients through web-based self audit and practice comparisons with professional peers (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 4/2015)
29. Accreditation for General Practices, After Hours and Medical Deputising Services and Special Interest Practices (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 5/2015)
30. BreastSurgANZ Quality Audit and Outlier Process (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 – QAA 6/2015)
31. The Radiological Events Register (RaER) by the Australian Patient Safety Patient Foundation (APSF) and Breast Screen Reader Assessment Strategy (BREAST) by The University of Sydney, Image Optimisation and Perception, Medical Imaging and Radiation Sciences and BreastScreen Australia (Instrument No QAA 2/2012 Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973)

32. Incident Recording and Reporting Program by the Australian and New Zealand Tripartite Anaesthetic Data Committee (ANZTADC) (Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act 1973 QAA 1/2013)
33. CareTrack Australia (Declaration of Quality Assurance Activity under section 124X QAA No. 3/2010)
34. Rural Craft Group Audit (Declaration of Quality Assurance Activity under section 124X QAA No. 3/2009)
35. Perinatal mortality and morbidity: Learning from adverse events to improve care and Nuchal Translucency – Ultrasound, Education and Monitoring Program (Declaration of Quality Assurance Activity under section 124X QAA No. 1/2009)