Jurisdictional Legislative Requirements

National & State Statutory and Administrative Frameworks for Ethical Review of Multi-centre Human Research Projects

---

This document aims to provide an overview of the various legislative and administrative frameworks that currently exist in Commonwealth, States and Territories and apply to the approval of human research under Mutual Acceptance of Ethics and Scientific Review. This document is not a substitute for legal advice.

Information within this document refers to legislation of:
- Commonwealth of Australia
- Australian Capital Territory
- New South Wales
- Queensland
- South Australia
- Victoria
- Western Australia

Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) Schemes

	Jurisdiction	Statutes and Policies Relevant to Ethical Review	Application/Administrative Process: Instructions and Explanations
Clinical Trial Notification (CTN) Scheme	Commonwealth	*Therapeutic Goods Administration Act 1989 and Regulations*	Notification under the CTN Scheme (or application under the CTA Scheme) is required for: • any medicine or device not entered on the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or • the use of a registered medicine or device beyond the conditions of its marketing approval, including new indications extending the use of the product to a new population group and the extension of doses or duration of treatments outside the approved range. **Researcher**: The person responsible for the conduct of the clinical trial at a trial site. **HREC**: Responsible for assessing the scientific validity of the trial design, the safety and efficacy of the medicine or device and the ethical acceptability of the trial process, and for approval of the trial protocol. **Approving Authority**: The institution or organisation at which the trial will be conducted gives the final approval for the conduct of the trial at the site. **Sponsor**: The company, organisation, institution, body or individual (enterprise) that takes responsibility for the overall conduct of the trial. Notifies the TGA using the CTN form and paying the appropriate fee.
Clinical Trial Approval (CTA) Scheme	Commonwealth	*Therapeutic Goods Administration Act 1989 and Regulations*	Application under the CTA Scheme (or notification under the CTN Scheme) is required for: • any medicine or device not entered on the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or • the use of a registered medicine or device beyond the conditions of its marketing approval, including new indications extending the use of the product to a new population group and the extension of doses or duration of treatments outside the approved range. **Sponsor**: Submits an application to conduct clinical trials to the TGA for evaluation and comment. Completes Part 1 - the formal application, and Part 2 - Notification of the conduct of a trial under the CTA scheme **TGA**: Completes the evaluation of the trial and provides advice to the researcher. **Researcher**: A copy of the TGA advice must be provided to the reviewing HREC. Signs CTA Part 2 Section 2. **HREC**: Responsible for approving the proposed trial protocol after reviewing information received from the sponsor and investigator, and any additional comments from the TGA. Signs CTA Part 2 Section 3. HREC must ensure that TGA advice has been provided by researcher. **Approving Authority**: Signs CTA Part 2 Section 4.

Consent

	Jurisdiction	Statutes and Policies Relevant to Ethical Review	Application/Administrative Process: Instructions and Explanations
Consent and Impaired Capacity to Consent	Commonwealth		
	Australian Capital Territory	*Guardianship and Management of Property Act 1991* (ACT) *Medical Treatment (Health Directions) Act 2006* *Mental Health (Treatment and Care) Act 1994* *Powers of Attorney Act 2006* *Powers of Attorney Amendment Bill 2015*	May need to apply to ACT Civil and Administrative Tribunal for consent orders. ACT also allows for a competent individual to make a binding Health Direction which may restrict ability of a later appointed guardian to consent to certain treatment. Researchers should be aware of research definitions and supported consent mechanisms contained in the Amendment Bill.
	New South Wales	Part 5, *Guardianship Act 1987* (NSW)	The NSW Civil and Administrative Tribunal (NCAT) can approve a 'clinical trial' in which patients over the age of 16 but incapable of giving consent to medical or dental treatment can participate. Section 45AA(2) of the Guardianship Act sets out the matters the NCAT must be satisfied of before giving approval. The NCAT may also determine who may provide consent in an individual case – the 'person responsible' or the NCAT itself – as well as the sufficiency of the information to be provided informing consent of the 'person responsible'. [s45AB] Researcher must obtain approval by the HREC and then the NCAT for a clinical trial involving a person unable to consent as defined in the Act. The definition of 'clinical trial' has been interpreted broadly by the NCAT and researchers are advised that if they think they might be conducting a clinical trial where they intend to enrol participants who lack capacity to consent, they should approach the NCAT formally for its approval.
	Queensland	*Guardianship and Administration Act 2000* (Qld)	Following ethics approval and before commencing the approved research, where a person is over the legal age of consent but has impaired capacity to consent, written application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken by the researcher for the applicable clinical research. Pursuant to s72 of the Act, the research must relate to a condition which the adult has (or has a significant risk of being exposed to), or the research must be intended to gain knowledge in relation to that condition. The threshold to which QCAT must be satisfied is high.
	South Australia	*Guardianship and Administration Act 1993* (SA)	Any personal information regarding a person involved on proceedings under the Act cannot be released for research purposes. It can only be released in aggregate form e.g. the presentation of statistics. A person of or over 18 years of age may while of sound mind, give a direction under this section about the medical treatment that the person wants or does not want, if he or she is at some future time in the terminal phase of a terminal illness, or in a persistent vegetative state; and incapable of making decisions about medical treatment when the question of administering the treatment arises.
	Victoria	*Medical Treatment Planning and Decisions Act 2016 (Vic)*	Completion of the Victorian Specific Module will address State legislative requirements for HREC approval. Following ethics approval, in the case of 'procedural authorisation' where a medical research procedure on a patient is carried out by the practitioner or supervising practitioner (in Victoria) without consent under section 81 then a Section 81 Certificate must be completed and provide this to the Office of the Public Advocate and the reviewing HREC as soon as practicable.
	Western Australia	*Guardianship and Administration Act 1990* (WA) *Mental Health Act 2014* (WA)	The *Guardianship and Administration Act 1990* (Act) does not include a provision for consent by a substitute decision maker for a person to participate in medical research. Consent under the Act may only be provided by a substitute decision maker for a person to participate in treatment which is in the best interests of the patient. Consent to treatment under the Act can be given by the patient if the patient has made an appropriate advance health directive, by an appointed enduring guardian, a guardian, or another responsible person as defined in section 110ZD and prioritised in section 110ZJ of the Act. See the Public Advocate's Statement on Decisions about Treatment. Once the provisions of the Act have been satisfied such that the research is treatment which is in the best interests of the patient and the appropriate substitute decision maker under the Act has been identified, then the guidelines in the National Statement have application. If the research project intends to recruit persons in WA who may be deemed incapable (either mentally or physically) of providing consent the investigator will be required to provide the reviewing HREC with sufficient details to make an assessment of whether the provisions of the Act and the ethical requirements set out in the National Statement have been met. This must be documented in the Western Australian Specific Module (WASM) which accompanies the Human Research Ethics Application (HREA). Within the *Mental Health Act 2014* (ACT) the definition of a 'mental health service' and 'relevant information' applies to medical or epidemiological research related to mental illness. The provisions of the Act must be considered when disclosing relevant information.

Consent of Minors	Commonwealth	The common law applies in those Australian jurisdictions that have not specifically legislated in relation to the issue of minors' consent to medical treatment. Note: *Family Law Act 1975* (Cth) provisions. *National Statement on Ethical Conduct in Human Research* Chapter 2.2, 2.3 & 4.2	Consent for participation of minors in research is required from: (a) the child or young person, whenever they have the capacity to make this decision; and either (b) one parent, except when (in the opinion of the review body) the risks involved in the child's participation require the consent of both parents; or (where applicable) (c) a guardian or other primary caregiver, or any organisation or person required by law. Researcher must provide an explanation of why participation of children is indispensable to research & consent process, and prior to including a child or young person in research must establish that there is no reason to believe that such participation is contrary to that child's or young person's best interests. In the research design, researchers should: (a) specify how they will judge the child's vulnerability and capacity to consent to participation in research; (b) describe the form of proposed discussions with children about the research and its effects, at their level of comprehension; and (c) demonstrate that the requirements of Chapter 4.2 of the National Statement on Ethical Conduct in Human Research will be satisfied. In relation to consent by parents for participation in research by minor: Provides that each of the parents of a child has parental responsibility for that child, which includes the duties, powers, responsibilities and authority which parents have in relation to their children. [ss61B-61C]
	Australian Capital Territory	*Children and Young People Act 2008* (ACT)	Researcher must address in HREA whether any of the participants lack the capacity to give consent and how this will be managed.
	New South Wales	PD2005_406 *Consent to Medical Treatment*	PD2005_406 Consent to Medical Treatment The policy provides the age for which consent to medical treatment may be provided by a minor: • A child under the age of 14 years must have their parents' consent prior to receiving medical treatment. • A child over 14 years and older may consent to their own treatment provided they adequately understand and appreciate the nature and consequences of the treatment. • Where the child is aged 14 or 15, it is also prudent to seek the child's parents' consent. While the ages for consent to medical treatment may be used as a guide for minors' consent to research, it should be noted that a number of paediatric institutions in NSW consider the law unclear in this area and require the parents of all children/young persons under the age of 18 to provide consent for the child/young person's participation in research. Researchers should check these requirements with the site involved prior to developing a single Participant Information Sheet and Consent Form.
	Queensland	*Child Protection Act 1999* (Qld)	Section 8 of the *Child Protection Act 1999* (Qld) specifies that a person under 18 years is considered a child. No specific laws about minors and consent to medical treatment (note. s 189B of the *Child Protection Act 1999* specifies that the chief executive of the Department of Communities, Child Safety and Disability Services may authorise a researcher to have access to information, or to contact a child (or family etc) to ask if they would like to participate in the applicable clinical research). Common Law in relation to consent, and capacity to consent, applies for those under 18 years. Otherwise as per Commonwealth requirements.
	South Australia	Consent to Medical Treatment and Palliative Care Act (1995) Advance Care Directives Act (2013)	The CMTPCA provides that consent to medical treatment of a person who is 16 years or older who has impaired decision-making capacity may be given to a person responsible, e.g. a legal guardian. A person who has capacity and is 18 years or older may appoint a substitute decision maker under the provisions of the Advance Care Directives Act (see below) to make decisions and provide consent on their behalf in the event they become incapacitated. If the research involves or constitutes medical treatment the provisions of this Act must be followed. The ACD Act enables a person to express their wishes through an Advance Care Directive regarding their future medical care/treatment. This may have relevance to research where the research involves administration of a medical treatment/intervention, e.g. a clinical trial.
	Victoria	*Medical Treatment Planning and Decisions Act 2016 (Vic)* *Human Tissue Act 1982 (Vic)*	Completion of the Victorian Specific Module, to be submitted with the HREA, will address Victorian legislative requirements for HREC approval. Parent/guardian written consent for participants under 18 years of age A parent may give written consent for the removal of regenerative tissue from a child but only for the purposes of transplanting the tissue to a sibling or parent of the child. It is not lawful to remove non-regenerative tissue from the body of a living child for the purpose of the transplantation of the tissue to the body of another living person. For removal of blood from a child [a 'child' is defined as a person who has not attained the age of 16 years (Section 20A, *Human Tissue Act 1982*)]

	Western Australia	*Children and Community Services Act 2004* (WA) *Age of Majority Act 1972* (WA) *Working with Children (Criminal Record Checking) Act 2004* (WA)	The *Children and Community Services Act 2004* allows the Minister to enter into an agreement with a person to conduct research and development in relation to the provision of social services. The *Age of Majority Act 1972* allows persons of age of 18 years or more to have full legal capacity. Researchers must address in the HREA and the WASM how the recruitment of children and/or young people (under 18 years of age) will be managed. If the research involves direct contact with WA participants under 18 years of age the research is not considered low risk and therefore must undergo full HREC review. Some paediatric research in the form of chart reviews, retrospective studies, non-confrontational interviews with parents or other health professionals etc. may be considered as low risk. A Working with Children Check is required by a person if they engage in child-related work (refer to https://workingwithchildren.wa.gov.au/index) This must be addressed in the WA Site Specific Assessment Form.

Embryo Research

Jurisdiction	Statutes and Policies Relevant to Ethical Review	Application/Administrative Process: Instructions and Explanations
Commonwealth	*National Statement on Ethical Conduct in Human Research* Chapters 3.2, 3.4, 3.5, 3.6 & 4.1 may apply *Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research* *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* *Prohibition of Human Cloning for Reproduction Act 2002* *Research Involving Human Embryos Act 2002* *Research Involving Human Embryos Regulations 2003*	Researchers need to detail in HREA their knowledge of the requirement for relevant applications in accordance with the guidelines and legislation. **HREC review**: HREC must evaluate the research proposal according to the NHMRC Embryo Research Licensing Committee Information Kit Chapter 4: Information for human research ethics committee. The HREC must be satisfied that the activity or project has been designed so that proper consent is obtained from all responsible persons. A copy of the HREC's assessment and approval of the licence proposal should be provided to the NHMRC Licensing Committee, and should contain the following: • A statement that the HREC was constituted in accordance with the National Statement; • A statement that members fulfilling the required roles were present or had an opportunity to comment on the application; • A statement of how the application meets the requirements of the RIHE Act and relevant guidelines; and • A statement of how the consent process and documents will allow for proper consent to be obtained, in accordance with the ART Guidelines and the National Statement. **Researcher**: Applies for a licence to the NHMRC Licensing Committee to conduct embryo research post HREC approval. As a licence holder, the researcher must: (a) meet the requirements set out in Chapter 3 of the NHMRC Embryo Research Licensing Committee Information Kit; and (b) notify the NHMRC Licensing Committee that relevant consents have been obtained, and of any restrictions to which the consent is subject.
Australian Capital Territory	*Human Cloning and Embryo Research Act 2004*	Researchers need to detail in HREA their knowledge of the requirements and guidelines necessary to act within the legislation.
New South Wales	*Research Involving Human Embryos (New South Wales) Act 2003* *Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (NSW)*	NSW Acts ensure state compliance with national uniform laws.
	Assisted Reproductive Technology Act 2007 (NSW)	Consent from gamete provider required prior to an ART provider using a gamete or embryo for research. [s20] Prohibits an ART provider from obtaining a gamete from a child for research in connection with ART treatment. [s29]
Queensland	Commonwealth legislation *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* (Qld) *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2003* (Qld)	As per Commonwealth requirements.
South Australia	*Research Involving Human Embryos Act (2003) and Research Involving Human Embryos Reglations (2018)*	As per Commonwealth requirements. Includes specific requirements associated with the use of excess Assisted Reproductive Treatment (ART) embryos for research purposes, with reference to the role of the NHMRC Licensing Committee.

Victoria	*Research Involving Human Embryos Act 2008* (Vic) *Prohibition of Human Cloning for Reproduction Act 2008* (Vic) *Assisted Reproductive Treatment Act 2008* (Vic)	As per Commonwealth requirements.
Western Australia	*Human Reproductive Technology Act 1991* (WA) *Human Tissue and Transplant Act 1982* (WA)	As per Commonwealth requirements; and Under the *Human Reproductive Technology Act 1991* (HRT Act), the licensing scheme for research on excess Assisted Reproductive Technology (ART) embryos relies on the Commonwealth agreeing to undertake the licensing function. As the HRT Act is no longer a "corresponding State law", section 43 of the RIHE Act does not apply and there is no authority for the State law to confer powers on Commonwealth officers and the NHMRC Licensing Committee. This leaves the State law inoperative in respect of licensing of research on excess ART embryos, with the effect that excess ART embryo research cannot be licensed under the HRT Act. Under the HRT Act clinics must be licensed by the Chief Executive Officer (Director General, Department of Health). Under section 20 of the HRT Act, the approval of the Reproductive Technology Council is required in relation to research involving participants undergoing ART treatment, human gametes or embryos, but not for research involving an excess ART embryo (unless an exempt excess ART embryo under section 53W(2), in which case such approval is required, refer to http://www.rtc.org.au/information-for-clinics/). This approval must be submitted with the WA Site Specific Assessment Form. Within the *Human Tissue and Transplant Act 1982* research falls within the definition of 'therapeutic use' in relation to the use of embryonic stem cell lines. In some circumstances disclosure of information may be allowed for *bona fide* medical research.

Financial Accountability

Jurisdiction	Statutes and Policies Relevant to Ethical Review	Application/Administrative Process: Instructions and Explanations
Commonwealth	*National Statement on Ethical Conduct in Human Research* Section 1 Applicable funding policies and deed/s of agreement	Researchers need to detail in HREA their funding status. **HREC review** Review of adequate resources as per HREA
Australian Capital Territory	*Financial Management Act 1996*	Researchers need to detail in HREA their funding status. Required to submit detailed budget as found in ACT Health application form.
New South Wales	None specific to research	As per Commonwealth requirements. Financial accountability also assessed post-HREC approval in Site Specific Assessment Section 1.
Queensland	*Financial Accountability Act 2009* (Qld) *Financial and Performance Management Standard 2009* *Queensland Health Research Management Policy(QH-POL-013: 2015)* *Department of Health Financial Practice Manual* Site Specific Assessment Applicable funding policies and deed/s of agreement	As per Commonwealth requirements. General accountability obligations imposed on budget sector agencies and statutory bodies (not specific to research). In addition, financial accountability also assessed post HREC approval in Site Specific Assessment Form - Section 18
South Australia	*Public Finance and Audit Act 1987*	Part F3 Div 2 of the Public Finance and Audit Act 1987 The Auditor General must, if required by the Treasurer, examine the accounts of a publicly funded body and the efficiency and economy of its activities and examine accounts relating to a publicly funded project and the efficiency and cost-effectiveness of the project. Funding arrangements and financial accountability for the research project is also considered as part of the Site Specific Assessment process.
Victoria	None specific to research	As per Commonwealth requirements.
Western Australia	*Financial Management Act (2006) (WA)* *Health Services Act 2016 (WA)* *Treasurer's Instructions*	The *Health Services Act 2016* promotes effective, efficient and innovative research within the available financial and other resources. To enable this, researchers must comply with the requirements of the Financial Management Manual and provide a detailed authorised budget in the WA Budget Form associated with the Site Specific Assessment Form.

Gene Technology:
Research using gene technology i.e. any technique for the modification of genes or other genetic material; research involving Gene and related therapies and Stem cell-based cellular therapies

Jurisdiction	Statutes and Policies Relevant to Ethical Review	Application/Administrative Process: Instructions and Explanations
Commonwealth	*National Statement on Ethical Conduct in Human Research* Chapters 3.2, 3.4, 3.5, 3.6 & 4.1 may apply *Gene Technology Act 2000* *Gene Technology Regulations 2001* *Office of the Gene Technology Regulator (OGTR) Guidelines* *Therapeutic Goods Act 1989*	Research to which Chapter 3.5 of the National Statement applies must be reviewed and approved by a HREC rather than through any other process of ethical review, except where the research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review. Researchers need to detail in HREA their knowledge of the requirement for relevant applications in accordance with the guidelines and legislation. **Researcher**: • Where research may discover or generate information of potential importance to the future health of participants, or their blood relatives, researchers must prepare and follow an ethically defensible plan to disclose or withhold that information. • Consent should be sought from appropriate community representatives as well as from the individuals concerned, where: - researchers propose to collect genetic material and information from individuals who are chosen because of their membership of a particular community; - the research involves sensitivities for that community; and - there is known to be a culturally relevant community structure involved in such matters. • Approval must be granted by the relevant Institutional Biosafety Committee (IBC) • An application for a licence for dealings with a Genetically Modified Organism (GMO) not involving intentional release of the GMO into the environment (DNIR) OR a licence for dealings with a GMO involving intentional release of the GMO into the environment (DIR) must be submitted to the OGTR. **HREC review**: Ensure researchers have documented their awareness of their responsibilities in HREA
Australian Capital Territory	*Gene Technology Act 2003*	Ensure researchers have documented awareness of their responsibilities.
New South Wales	*Gene Technology (New South Wales) Act 2003 (NSW)*	NSW Act ensures state compliance with national uniform laws.
	Human Tissue Act 1983 (NSW)	National Statement [3.5.7] imposes conditions on which genetic material may be transferred. Where the genetic material is in the form of human tissue, the Human Tissue Act will apply, possibly imposing additional conditions.
Queensland	*Gene Technology Act 2001* (Qld) *Code of Ethical Practice for Biotechnology in Queensland (2006)*	As per Commonwealth requirements. The principles identified in the Code are integrity, beneficence and non-maleficence, respect for people, care and protection of animals, justice, and respect for the law and system of government.
South Australia	*Gene Technology Act (2001) SA* *Gene Technology Regulations (2017) (SA)*	As per Commonwealth requirements.
Victoria	*Gene Technology Act 2001 (Vic)*	As per Commonwealth requirements.
Western Australia	*Gene Technology Act 2006* (WA)	As per Commonwealth requirements.

Ionising Radiation:
Procedures involving use of ionising radiation that are performed specifically for research

Jurisdiction	Statutes and Policies Relevant to Ethical Review	Application/Administrative Process: Instructions and Explanations
Commonwealth	*Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice for Exposure of Humans to Ionizing Radiation for Research Purposes 2005* *ARPANSA Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation 2008*	**Researcher**: The researcher must comply with the requirements. Section 2.1.6 of the *ARPANSA Code of Practice for Exposure of Humans to Ionizing Radiation for Research Purposes* states that a researcher must obtain an independent assessment or verification by a Medical Physicist of the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol. Researchers need to provide the independent assessment report and detail in HREA the assessment process undertaken under the ARPANSA Code. In addition, the researcher's submission to the HREC must include the following information regarding radiation exposure: (a) why it is necessary to expose participants to ionizing radiation for the purpose of the research; (b) the radiation dose assessment and risk assessment as assessed or verified by the medical physicist; (c) a statement confirming that the site at which the examination or procedure will be performed is actively involved in a relevant quality assurance program; (d) the precautions to be taken to keep radiation exposure to a minimum; (e) the written information to be given to research participants relating to the doses and risks associated with the radiation exposure; and (f) for novel uses of radiation, the arrangements for a review of radiation doses actually received and the arrangements for retention of dose records. **HREC review**: The researcher must ensure that the independent assessment report has been submitted to the reviewing HREC with research application. The HREC should consider the balance between the likely benefits and risks associated with any radiation exposure, including the information attached to the ARPANSA Code at Annex 1. The HREC should pay particular attention to: (a) the estimates of expected radiation doses and associated risks, which must have been calculated or verified by a medical physicist; (b) the dose estimates and radiation risk assessments and opinion of an independent medical physicist where the dose constraints are exceeded; (c) the manner in which the radiation doses and risks are provided to the research participants in the information sheet; (d) the justification for the radiation exposure, particularly if the radiation dose exceeds the dose constraints in the table set out in the ARPANSA Code; and (e) the measures to be taken during the project to assess the radiation doses actually received from novel uses of radiation where these may differ from the expected radiation doses and the arrangements for the retention of records of these doses.
Australian Capital Territory	*Radiation Protection Act 2006 (ACT)* Australian Radiation Protection and Nuclear Safety Agency Website: www.arpansa.gov.au/pubs/rps/rps8.pdf	Researchers are required to comply with these Regulations where undertaking research involving ionising radiation. Approval from Radiation Safety Officer is required with application.
New South Wales	*Radiation Control Act 1990* (NSW) *Radiation Control Regulation* 2003 (NSW)	Reinforces primacy of ARPaNSA document '*Administration of Ionizing Radiation to Human Subjects in Medical Research*' in determining doses of ionizing radiation exposure for persons involved in scientific or research purposes. [cl22] Clause 33 of the Regulations now governs voluntary exposure to radiation for scientific and research purposes. This must comply with the "Code of Practice for the Exposure of Humans to Ionising Radiation" as published by ARPANSA.

Queensland	Commonwealth legislation *Radiation Safety Act 1999* (Qld) *Radiation Safety Regulation 2010* (Qld) Applicable Radiation Safety Standards	Possession and use of a radiation source must be licensed under the *Radiation Safety Act 1999* (Qld), and if required under that Act, a certificate of compliance must also be obtained. Pursuant to Part 6 of that Act, a Radiation Safety and Protection Plan must be approved by the Chief Executive, Queensland Health, before a possession licence will be granted. Otherwise as per Commonwealth requirements.
South Australia	*Radiation Protection and Control (Ionising Radiation) Regulations, 2015*	Commonwealth ARPANSA requirements must be followed, specifically the equirements of the "Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)". The Code of Practice sets out a various responsibilities and processes in relation to research involving exposure to ionising radiation. Part 3, Division 2, of the Regulations sets out the Ministerial approval required for those undertaking research involving ionising radiation, including the specific application requirements.
Victoria	*Radiation Act 2005* (Vic)	An institution in Victoria that administers ionising radiation to humans for research purposes must be licensed with the Victorian Department of Health. If the research project's dose of radiation is above the dose constraint of Table 1 of the ARPANSA Code and approval has been given by the HREC, then the organisation (licence holder) providing research governance/SSA authorisation must notify the Radiation Team, Department of Health, within 14 days of research governance/SSA authorisation. The project may commence prior to notification being submitted to Department of Health. For details of dose constraints, refer to the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes 2005* . For information on Victorian radiation regulations, visit https://www.health.vic.gov.au/public-health/radiation.
Western Australia	*Radiation Safety Act 1975 (WA)* *Radiation Safety (General) Regulations 1983 (WA)*	As per Commonwealth requirements; and The Radiological Council of Western Australia requires a Radiation Safety Officer to review the research protocol and radiation dosimetry assessment (prepared by a Medical Physicist). Research that involves participant radiation exposure greater than 5mSv (if radiation is over and above standard of care) will generally be required to be submitted to the Radiological Council for approval. The institution's Medical Physicist with the Radiation Safety Officer will decide if this is required and will advise the researchers and submit the application to the Radiological Council. The Medical Physicist report and the Radiological Council approval (if relevant) must be submitted with the WA Site Specific Assessment Form.

Privacy and Confidentiality

Jurisdiction	Statutes and Policies Relevant to Ethical Review	Application/Administrative Process: Instructions and Explanations
Commonwealth	*Privacy Act 1988* National Privacy Principles NHMRC Guidelines approved under sections 95, 95A of the *Privacy Act*. *Australian Institution of Health and Welfare Act 1987*	A researcher must provide the HREC with the material required under the NHMRC Guidelines, including any information necessary to enable the HREC to perform its obligations under the Guidelines. The researcher must explain how health information held by the Australian Government will be used or disclosed during the research and that this conforms to the legislative requirements. The HREC must, in making a decision under the NHMRC Guidelines, consider the following matters: (a) identify and consider the IPP or IPPs that might be breached in the course of the proposed research, including whether it is necessary for the research to use identified or potentially identifiable data, and whether it is reasonable for the research to proceed without the consent of the individuals to whom the information relates; (b) ensure that the committee has the competence to determine if the public interest in the proposed research outweighs, or does not outweigh, to a substantial degree, the public interest in the protection of privacy. If the public interest in the proposed research does not outweigh, to a substantial degree, the public interest in the protection of privacy, the research should not be carried out. In reaching this decision, the HREC must have regard to the factors set out in the NHMRC Guidelines. The HREC must also consider whether the proposal complies with the relevant NPPs in respect of the collection, use and disclosure of health information for relevant purposes. The HREC must monitor proposals approved under the NHMRC Guidelines. Institutions and researchers must ensure health information is collected, used and disclosed in accordance with the Guidelines approved under sections 95 and 95A of the *Privacy Act*. Researchers must seek approval from the AIHW Ethics Committee for access to data held by the institute (section 29(2)(c)), and must ensure that it does not disclose any such information to any person unless the AIHW Ethics Committee has specified in writing that such disclosure is permitted.
Australian Capital Territory	*Health Records (Privacy and Access) Act 1997* *Public Health Act 1997* *Adoption Act 1993*	As per Commonwealth requirements. Health and mental health information may be disclosed to a medical practitioner by authority of an applicant under the act (s65).
New South Wales	*Health Records and Information Privacy Act 2002* (NSW); *Statutory Guidelines on Research*	Regulates personal health information in both public and private sectors in NSW. Health Privacy Principles (HPPs) prescribe limits on the use and disclosure of health information for a purpose other than that for which it was collected, unless that use, amongst other things: Is reasonably necessary for research or the compilation or analysis of statistics that is in the public interest. Before this exception can be applied, certain preconditions must be met: • The use or disclosure is reasonably necessary for the purpose; • The purpose cannot be served by de-identified information; • It is impracticable to seek the person's consent; • Reasonable steps have been taken to de-identify the information; • Information that can be reasonably expected to identity individuals is not published in a generally available publication. • Certain Statutory Guidelines issued by the Privacy Commissioner must be met. These Guidelines are essentially the same as the Guidelines developed for s95 & s95A of the *Privacy Act 1988* (Cth). Research requiring use or disclosure of personal health information will need to be considered by a Health Research Ethics Committee who will apply the test set out in the Act. The reviewing HREC and its organisation must report to the NSW Privacy Commissioner on an annual basis even where that HREC is outside NSW.
	Health Administration Regulation 2010	Prescribes circumstances in which disclosure of information in connection with the administration or execution of the *Health Administration Act 1982* (NSW) may be made generally and for the purposes of medical research. [cl16]
	Mental Health Act 2007 (NSW)	Creates an offence for disclosing information obtained in connection with the Act, unless certain provisions are met, which includes a purpose referred to in the HRIP Act HPPs relating to research. [s189].

	Parliamentary Electorates and Elections Act 1912 (NSW)	Procedure to be undertaken by Electoral Commissioner in response to a request for information from electoral roll, including format of information that may be provided to medical researchers. [s41]
	Public Health Act 2010 (NSW)	Allows for the use of information held in the Pap Test Register to be used for the purpose of maintaining a (non-identifying) database for use in research in the prevention and treatment of cervical cancer. [s91]
Queensland	*Information Privacy Act 2009* (Qld) *Information Standard 42A - Information Privacy Guidelines*	Researchers ought to be aware that NPP 2(1)(c) restricts Queensland Health to only disclose personal information about an individual where that use or disclosure is necessary for research that is relevant to public health and safety. The health agency may, in this situation, disclose personal information where it is impractical to seek consent beforehand, and the disclosure is accordance with a guideline that has been approved by the chief executive of QH. QH must also be satistfiefd that the researcher will not disclose that information in turn. For these purposes, 'personal information' is taken to mean any information or an opinion about an individual whose identity is apparent, or can reasonably be attained, Researchers should keep in mind however that, in the event of any inconsistency, the confidentiality provisions from the HHB Act (outlined below) will prevail over those outlined in this section above.
	Public Health Act 2005 (Qld) *('PHA')*	A researcher may make an application under s282 of the PHA to the chief executive of Queensland Health to be given access to information for research purposes. The application must clearly set out (among other particulars specified in s282) the purpose and methodology of the research, as well as how the privacy of any identified individuals will be protected. The application must also state the views of a HREC on the research. In deciding the outcome of any application the chief executive of QH will have regard to the opportunities the research will provide for increasing knowledge and improved health outcomes, as well as privacy of those individuals identified. s291 of the PHA requires that a researcher not disclose the abovementioned health information without the written consent of the individual identified, or in instances where the information is suitably de-identified. Keep in mind that the provisions in s142 of the HHB Act (discussed below) do not apply to information given under the PHA. HREC review: Ensure researchers have detailed their knowledge of the requirements under the PHA, if applicable to project. Researchers need to detail in HREA their knowledge of the requirement for a PHA application post HREC approval.
	Hospital and Health Boards Act 2011 (Qld) *('HHB Act')*	Part 7 of the HHB Act relates to confidentiality and provides several exceptions to the rule in s 142 that confidential information must not be disclosed unless required or permitted under the HHB Act. Confidential information is defined as information from which a person's identity could be identified.Of particular interest to researches may be s 144 which allows for disclosure of confidential information with the persons consent.
South Australia	*Mental Health Act (2009)* (s106)	Permits disclosure of personal information for "social or medical research purposes if the research methodology has been approved by an ethics committee and there is no reason to believe that the disclosure would be contrary to the person's best interests".
	SA Health Care Act (2008) (s93)	Permits disclosure of personal information for "social or medical research purposes if the research methodology has been approved by an ethics committee and there is no reason to believe that the disclosure would be contrary to the person's best interests".
	Assisted Reproductive Treatment Act (1988)	Includes provisions for the responsible Minister to authorise the use of non-identifiable statistical information for research and education purposes linked with donors of human reproductive materials.
	Guardianship and Administration Act (1993) and Guardianship and Administration Regulations (2015)	Prevents the disclosure of personal information regarding a person involved in proceedings under the Act for research purposes. Such information can only be released in aggregate form e.g. the presentation of statistics.
	Transplantation and Anatomy Act (1993) (s39)	Permits disclosure of personal information for bona fide medical research from a person from whose tissue has been used for transplantation or related purposes, where consent is provided.
Victoria	*Health Records Act 2001* (Vic) *Privacy and Data Protection Act 2014* (Vic)	Completion of the Victorian Specific Module, to be submitted with the HREA, will address Victorian legislative requirements for HREC review.
Western Australia	*Freedom of Information Act 1992* (WA) *Health Service Act 2016* (WA) *Public Sector Management Act 1994* (WA) *State Records Act 2000* (WA)	As per the Commonwealth requirements; and WA information must be used and disclosed for research in accordance with the Health Service Act 2016 and Information Access, Use and Disclosure Policy 2017. Under the Public Sector Management Act 1994 WA Health employees must comply with the WA Health Code of Conduct to maintain confidentiality of personal or other information. External research personnel who will be either conducting a research project within WA Health or accessing WA Health participants, their tissue or data for a research project must submit the WA Health Declaration of Confidentiality and/or the Student Research and Confidentiality Declaration with the WA Site Specific Assessment Form.

Record Keeping

Jurisdiction	Statutes and Policies Relevant to Ethical Review	Application/Administrative Process: Instructions and Explanations
Commonwealth	*Archives Act 1983*	Relevant documents in the custody of a Commonwealth institution may be required to be dealt with in accordance with the Archives Act.
	Therapeutic Goods Administration: Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments	GCP: Requires sponsors to retain records for 15 years following the completion of clinical trials regulated by the TGA. However, the TGA also notes that the overriding consideration for sponsors with respect to record retention is the issue of product liability and the potential need to produce records at any time during, and possibly beyond, the life of a product in the event of a claim as a result of an adverse outcome associated with the use of the product.
	Australian Code for the Responsible Conduct of Research : Section 2.1	The Code describes differing lengths of time for retention of research data dependent on the type of research being conducted.
Australian Capital Territory	*Territory Records Act 2002* *Health Records (Privacy and Access) Act 1997*	Researchers to be aware of requirements under the act.
New South Wales	*State Records Act 1998* (NSW)	Under s21(2) of the Act, no part of the NSW public health system will be in breach of the Act if it complies with the General Retention and Disposal Authority: Public Health Services: Patient/Client records.
	General Retention and Disposal Authority: Public Health Services Patient/Client Records (GDA17) Administrative Records (GDA21)	GDA17: Disposal classes 8.0.0 – 8.1.5 (Research Management) deal with records created for the management of the conduct of clinical and non-clinical research, trials or studies, etc. Disposal actions (including timeframes for retention) are listed against each disposal class. GDA21: Disposal classes 15.0.0 – 15.6.3 (Research Management) deal with records created for the management of the conduct and operations of projects, programs, trials or studies conducted for the purposes of advancing medical knowledge. Disposal class 5.3.3 deals with records relating to the establishment and meetings of ethics/research committees. Disposal actions (including timeframes for retention) are listed against each disposal class.
Queensland	*Queensland Health Sector (Clinical Records) Retention and Disposal Schedule (2012)* *Public Records Act 2002 (QLD)*	Queensland Health is required to make and keep full and accurate records of its activities under the Public Records Act. These records may be transferred to the archives if they are over 25 years old. In relation to specific health records, the QH schedule should be followed. It provides that, for clinical research, records must be retained for 15 years from completion of research *and* 10 years after last patient/client service provision. Where there is no direction under the QH schedule then follow Commonwealth requirements.
South Australia	*State Records Act 1977*	Outlines retention and disposal requirements for records, including those pertaining to research, held by South Australian public sector agencies.
	South Australian Clinical and Client-Related Records of Public Health Units in South Australia - General Disposal Schedule 28 (section 6).	Applies to the records created or received by the current South Australian Local Health Networks and their predecessors. Outlines the record keeping and data retention requirements for researchers, including employees of the South Australian public health system and externally employed researchers (where applicable), undertaking health and medical research involving SA public health organisations, including the use of SA public health organisation and patient data. Aligns with NHMRC and "Australian Code" requirements, where appropriate.
Victoria	*Health Records Act 2001* (Vic)	Refer to the Guidelines for the Victorian Specific Module to address Victorian legislative requirements for HREC review.
Western Australia	*State Records Act 2000* (WA)	Section 19 of the *State Records Act 2000* requires that every government organisation must have a Recordkeeping Plan. The WA Health Recordkeeping Plan documents suitable security arrangements for storage of paper-based and electronic information for all types of records (patient, administrative, financial, human resource management). The *Patient Information Retention and Disposal Schedule 2016* (Index No. 5.7) covers research records related to patient/subject records, consent and research requests.

Removal and Use of Human Tissue

	Jurisdiction	Statutes and Policies Relevant to Ethical Review	Application/Administrative Process: Instructions and Explanations
Removal and Use of Human Tissue (Excluding Blood) from a Living Person	Commonwealth	*National Statement on Ethical Conduct in Human Research* Chapters 3.1, 3.4, 3.5, 3.6 & 4.1 may apply	Institutions are required to develop a policy for the collection, storage, use and disposal of human tissue in research, covering the issues set out in section 3.4.1 of the National Statement. Researchers should demonstrate that tissues will be collected, stored, used and disposed of in accordance with this policy. Where tissue is imported from another country for use in Australia, researchers should try to establish whether there are ethical and professional policies in that country, or the relevant institution, governing the collection of tissue for use in research. (a) Where such a policy exists, and reasonable enquiry reveals no reason to believe the collection of the tissue contravened it, the HREC may consider waiving consent for the use of the tissue in accordance with section 2.3.6 of the National Statement. (b) Where it cannot be established that a policy exists, or where it exists but enquiry reveals reason to believe that the tissue was not collected in accordance with it, the tissue should not be used in research in Australia. (c) For research with tissues that were in collections either imported or existing overseas before the release of the National Statement, the HREC may consider waiving consent without reference to paragraphs (a) and (b) above. Consent for the use of tissue may be specific, extended or unspecified. Where consent is given for the use of human tissue in specific research only, that tissue should not be used for any other purpose without the consent of the tissue donor unless an HREC or other review body has waived the requirement to seek further consent.
	Australian Capital Territory	*Transplatation and Anatomy Act 1978* (ACT)	
	New South Wales	*Human Tissue Act 1983* (NSW); *Statutory Guidelines on Research*	Amendments to *Human Tissue Act* (HTA) in 2003 create requirements for consent to the use of human tissue for research purposes. Section 34A of the Act relates to research. Amendments are not retrospective so different consent requirements exist for tissue removed prior to, and after, 1 November 2003.
		NSW Health Policy Directive PD2005_341	NSW Health Policy Directive *PD2005_341 Human Tissue-Use/Retention Including Organ Donation, Post-Mortem Examination and Coronial Matters* outlines *Human Tissue Act* requirements and NSW Health policy in relation to the provision of information and obtaining consent for use of human tissue.
		NSW Health Policy Guideline GL2006_021	NSW Health Guideline *GL2006_021 Human Tissue - Requirements of the Human Tissue Act 1983* in relation to research & use of tissue Provides guidance for HRECs by outlining the research requirements of the HTA.
	Queensland	*Transplantation and Anatomy Act 1979* (Qld)	Consent to removal of tissue for research purposes must be given in writing, and a certificate regarding consent given by a designated officer. The terms of the participant's consent must be set out in the certificate issued by the designated officer. Accordingly, specific directions re consent for the use of tissue for future research should be documented. Researchers ought to note that different rules apply for regenerative and non-regenerative tissue. Researchers ought to also note the prohibitions with respect to the trading of tissue. Specific requirements within the Act regarding provision of tissue for research on a 'cost recovery' basis by prescribed tissue banks **HREC review**: Nil specific Also assessed under Section 9 and 10 of the Site Specific Assessment post-HREC approval.
	South Australia		Refer to relevant provisions of the National Statement including consent requirements. The SA Health 'Guidance Document for Human Research Biobanks and Associated Data' should be referred to where tissue is proposed to be stored in a biobank.
	Victoria	*Human Tissue Act 1982* (Vic)	Completion of the Victorian Specific Module to be submitted with the HREA. This will address Victorian legislative requirements for HREC review.
	Western Australia	*Human Tissue and Transplant Act 1982* (WA)	The *Human Tissue and Transplant Act 1982* (ACT) specifies regenerative and non-regenerative tissue as opposed to tissue generally. The Act specifies that tissues may only be removed by a medical practitioner or designated officer. A person shall not remove tissue other than blood from the body of a living person for use for a purpose specified in sections 8 (regenerative tissue), 9 (non-regenerative tissue) or 13 (regenerative tissue from a child) except in pursuance of a consent or authority that is under Division 4 of Part II sufficient authority for the person to remove the tissue for use for that purpose.

Removal and Use of Human Tissue (Excluding Blood) from a Deceased Person	Commonwealth	*National Statement on Ethical Conduct in Human Research* Chapters 3.2, 3.4, 3.5, 3.6 & 4.1 may apply	In addition to the general requirements in relation to the use of human tissue for research purposes, any wish expressed by a person about the use of his or her post-mortem tissue should be respected. If no such wish is discovered, consent for the use of the tissue should be sought from the senior available next of kin. At the time of seeking such consent, it should be agreed with the next of kin how the tissue is to be disposed of when the research is completed. Researchers should try to accommodate any reasonable wishes of next of kin in this regard.
	Australian Capital Territory	*Transplatation and Anatomy Act 1978* (ACT)	
	New South Wales	*Human Tissue Act 1983* (NSW); *Statutory Guidelines on Research*	Amendments to *Human Tissue Act* (HTA) in 2003 create requirements for consent to the use of human tissue for research purposes. Section 34A of the Act relates to research. Amendments are not retrospective so different consent requirements exist for tissue removed prior to, and after, 1 November 2003.
		NSW Health Policy Directive PD2005_341	*NSW Health Policy Directive* PD2005_341 Human Tissue-Use/Retention Including Organ Donation, Post-Mortem Examination and Coronial Matters outlines *Human Tissue Act* requirements and NSW Health policy in relation to the provision of information and obtaining consent for use of human tissue.
		NSW Health Policy Guideline GL2006_021	*NSW Health Guideline GL2006_021 Human Tissue - Requirements of the Human Tissue Act 1983* in relation to research & use of tissue Provides guidance for HRECs by outlining the research requirements of the HTA.
		Anatomy Act 1977 (NSW)	Sets out consent and authorisation requirements where anatomical examination for research precedes the removal of human tissue.
		Coroners Act 2009	Offence for human remains to be handed over for medical research without an 'appropriate disposal authorisation'. [s100(2)]
	Queensland	*Transplantation and Anatomy Act 1979* (Qld) See also Coronial material: *Coroners Act 2003* (Qld)	Removal of tissue from a deceased person is authorised if the person during their lifetime consented (signed and in writing) to such removal after death, and such consent has not been revoked. If there is no such written document, provided there is no reason to believe the person objected to removal of tissue after death then written consent must be obtained from the senior next of kin (or if the circumstances make written consent impracticable, oral consent from the senior next of kin may be given provided the fact and details of the consent are documented in the hospital record, and reasonable attempts are made to have the oral consent confirmed in writing by the senior next of kin). Researchers should also note s 53 of the *Coroners Act 2003* (Qld) which applies to access to any investigation material in possession of the coroner. Specific requirements within the Act regarding provision of tissue for research on a 'cost recovery' basis by prescribed tissue banks **HREC review**: If accessing coronial material, application can only be reviewed and approved by the QH FSS-HEC Also assessed under Section 9 and 10 of the Site Specific Assessment post-HREC approval.
	South Australia		Refer to relevant provisions of the National Statement including consent requirements. The SA Health 'Guidance Document for Human Research Biobanks and Associated Data' should be referred to where tissue is proposed to be stored in a biobank.
	Victoria	*Human Tissue Act 1982* (Vic)	Completion of the Victorian Specific Module, to be submitted with the HREA, will address Victorian legislative requirements for HREC review.
	Western Australia	*Coroners Act 1996* (WA) *Human Tissue and Transplant Act 1982* (WA)	Under the *Coroners Act 1996* there are situations when the Coroner's approval is required, notwithstanding consent from family or patient. Access to tissue samples and information from coronial post-mortems must be approved by the WA Coronial Ethics Committee. If the project involves the use of tissue samples taken during a non-coronial post-mortem, investigators must comply with the *Non-Coronial Post-mortem Examinations Code of Practice 2007* (enacted under the *Human Tissue and Transplant Act 1982*). The application for use of tissue from persons who were the subject of a post mortem must be documented in the Western Australian Specific Module (WASM) which accompanies the Human Research Ethics Application (HREA). The *Human Tissue and Transplant Act 1982* (ACT) specifies regenerative and non-regenerative tissue as opposed to tissue generally. The Act specifies that tissues may only be removed by a medical practitioner or designated officer.

Risk Management

Jurisdiction	Statutes and Policies Relevant to Ethical Review	Application/Administrative Process: Instructions and Explanations
Commonwealth	*National Statement on Ethical Conduct in Human Research* Chapter 2.1 TGA: *The Australian Clinical Trial Handbook* (March 2018)	Prior to endorsing any trial, the HREC must be satisfied that (among other things): (a) There is adequate expertise available to advise on the safety of the medicinal products or other interventions available; and (b) procedures are in place for regular reporting of trial progress; serious or unexpected adverse event reporting, reporting of significant new information regarding the trial products; reporting of premature trial discontinuation and, in the case of medical devices, that a system is in place to track the recipient for the lifetime of the device.
Australian Capital Territory		As per Commonwealth requirements.
New South Wales	*Risk Management - Enterprise-Wide Policy and Framework-NSW Health* PD2009_039 (2009)	This general risk management policy sets out the requirement for each NSW Health entity to implement a risk management framework in line with standards established by the relevant Australia and New Zealand Standard on *Risk Management*.
Queensland	*Queensland Health Risk Management Policy QH-POL-070:2015 (2015)*	Researchers have an obligation in designing a research project to minimise the risks to participants. Researcher must address in NEAF the applicable levels of risk, and how these will be managed. **HREC review**: Assessment of risks vs benefits. The HREC must conduct ethical and scientific review of research proposals in line with the NHMRC National Guidelines and the QH Research Management Policy and its Implementation Standards. The assessment process must be transparent and defensible.
South Australia		As per Commonwealth requirements, along with SA Health Research Ethics and Governance Policy requirements, the latter of which includes conflict of interest declaration requirements. In addition, the applicable SA Health policy directive and framework linked to risk management must be adhered to by all SA public health organisations and extends to include research activity.
Victoria		As per Commonwealth requirements. For a clinical trial conducted at a Victorian public hospital, it may be necessary to consult or notify the Victorian Managed Insurance Authority.
Western Australia	*Health Services Act 2016 (WA)* *Financial Management Act 2006 (WA)*	As per Commonwealth requirements; and In compliance with the *Health Services Act 2016* and *Financial Management Act 2006,* the *WA Health Risk Management Policy 2016* ensures management positions focus on material risks at all levels of their organisation and take necessary action to manage those risks. To enable this, researchers must complete the WA Site Specific Assessment and Budget Form and ensure they are authorised by WA Health management and executive personnel.

Jurisdictional Data Collections

Jurisdiction	Statutes and Policies Relevant to Ethical Review	Application/Administrative Process: Instructions and Explanations
Australian Capital Territory		All research project requiring access (including linkage) to data collections owned or managed by ACT Health or the Capital Region Cancer Service must be reviewed by ACT Health HREC.
New South Wales	PD2010_055 – *Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations*	All research projects requiring access (including linkage) to statewide data collections owned or managed by NSW Health or the Cancer Institute NSW must be reviewed by the NSW Population and Health Services Research HREC.
Queensland	*Public Health Act (PHA) 2005* may apply	If a researcher seeks access to information held by Queensland Health for research using identifiable or potentially re-identifiable health information for which the researchers are unable to obtain participant consent to use the personal or identifying information for a clearly specified research study, the researcher must make application to the Department under section 282 of the PHA.
South Australia	SA Health Research Ethics Operational Policy	Stipulates that human research ethics applications involving access to a database or data registry held by a public health organisation should be submitted to the affiliated HREC, where possible.Any multi-site or whole of state project where the primary data being used for the project is held centrally by the Department for Health and Wellbeing (DHW) (e.g. inpatient separations data) may be submitted to the DHW HREC for review as the lead HREC.
	Public Sector (Data Sharing) Act 2016	Supports sharing of administrative data across SA public agencies where a range of requirements are satisfied. This may extend to the use of data for research and evaluation purposes.
Victoria	Department of Health policy	To access data held by the Department of Health (DH), departmental notification and endorsement is required prior to an ethics application being submitted for review. Researchers must comply with the standard release conditions imposed by the Heads of the relevant DH program areas, who have ultimate responsibility for the appropriate storage, handling of, access to and use of the data of which they are custodians (Ch 3.2 National Statement). Contact The Centre for Victorian Data Linkage (CVDL) at cvdl@health.vic.gov.au
Western Australia	*Freedom of Information Act 1992* (WA) *Health Service Act 2016* (WA)	WA information must be used and disclosed for research in accordance with the Health Service Act 2016 and Information Access, Use and Disclosure Policy 2017. In accordance with the WA Health Research Policy Framework,researchers wishing to access personal health information from the Department of Health WA data collections or require data linkage must obtain approval from the Department of Health WA HREC. This application to access or link data must be documented in the Western Australian Specific Module (WASM) which accompanies the Human Research Ethics Application (HREA).