Government of **Western Australia**
Department of **Health**

Artificial Intelligence Standard

Digital Health Unit
September 2025

Artificial Intelligence Standard

Classification:
MP Official

health.wa.gov.au

This standard supports the application of MP 0193/25 *Artificial Intelligence Policy*.

1. Purpose

The purpose of the Artificial Intelligence (AI) Standard (this standard) is to support WA health staff in the safe and responsible use of AI. This standard should be read in conjunction with MP 0193/25 *Artificial Intelligence Policy*.

In implementing AI systems, staff should also refer to local Health Service Provider contacts for local processes and subject matter experts if needed.

2. Context

WA health entities recognise the significant opportunities presented by "AI". In healthcare, AI has potential to augment clinicians' expertise in diagnosis and treatment, accelerate medical research and drug development, enhance public health programs, and streamline administrative and analytical functions. AI is already being used in a range of WA health settings to improve responsiveness and accuracy in disease detection and patient monitoring.

However, while the potential opportunities may be numerous, governments worldwide have moved to regulate and define principles for AI, to guard against unintended or hazardous outcomes, and ensure public confidence and trust. AI introduces unique risks, adds complexity and sometimes cost, and needs to be well-understood by all responsible parties. Considerable care is needed to ensure safety, accuracy, equity, security and privacy, and it is critical that WA health entities build organisational maturity and workforce capability to plan, govern and implement the technology most effectively. Staff must be informed of appropriate uses of any AI systems available to them.

It should be noted that there is work underway nationally and internationally to further develop technology and regulation, which may change the policy and strategic environment. This standard will be updated as necessary as the external environment changes. As WA health entities are accountable for their regulatory compliance, they should also maintain an awareness of these.

3. Applicability

This standard is applicable to WA health entities.

4. Scope

AI systems included in this document are defined in section 5. What is an AI system?. Use of AI systems includes individual, corporate, clinical, pilot/trial, training or research purposes, and whether free of charge, developed in-house, purchased (buy and train, buy and automate, buy and use) or cloud-based software. It also includes the use of AI on private devices for a WA health work-related purpose.

The standard applies to all stages of the AI lifecycle including design, data, and modelling; development and validation; deployment; monitoring; refinement; and decommissioning.

5. What is an AI system?

The AI Policy and AI Standard have adopted the Office of Digital Government (DGov) definition of "AI systems" (see Definitions) which references ISO/IEC 22989:2022.

In general, AI systems refer to machines that can simulate an element of human capability. To be considered AI, AI systems would exhibit some level of learning, reasoning and adapting. AI techniques include symbolic AI, machine learning and deep learning. Table 1 provides examples of AI systems that may be relevant in a health context.

Early Internet of Things (IoT) devices, Robotic Process Automation (RPA) software, digital writing assistants, Optical Character Recognition (OCR) programs, statistical packages and other automated decision-making systems were not considered AI as they were not learning and adapting to make their own decisions. However, the growth of the AI industry has meant that many of these systems now claim to contain AI algorithms. This may or may not be true, so users should be aware when deciding to use the system or specific functions.

Users should also be aware that the use of any automated decision-making systems is subject to the *Privacy and Responsible Sharing Act 2024*. This highlights the overlapping risks across these technologies related to human ethics, accuracy and accountability. For consistency and responsible management of risk, WA health entities are asked to apply this AI Standard to other automated decision-making systems with an elevated risk.

Table 1. Examples of AI Systems

Symbolic AI	Machine Learning	Deep Learning
Also known as "traditional AI". Uses knowledge representation and logic-based programming.	Sub-field of AI. Applies algorithms and statistical models to large datasets to identify patterns and make predictions or decisions about new data.	Sub-field of Machine Learning. Uses deep neural networks similar to the human brain to analyse complex relationships and weigh up how to provide a response.
Examples: • AI chatbots that identify customer intent and mimic human-like conversations to provide health information. • Generative AI using large language models, which can create text, images & video from prompts.	• Drug discovery using machine learning of large-scale biological data. • Computer vision systems recognise objects and patterns in images, eg. scanning for medical conditions.	• Clinical decision-support systems that suggest diagnoses and tests based on patient symptoms, disease information and treatment pathways. • Deep learning companion robots that can "see" and understand its environment.

• Spam, fraud and cyber threat detection through patterns in network or financial transactions.	• Scribing tools that use natural language processing to generate notes and other documentation.

6. Acceptable Use of AI

6.1 Overall Acceptable Use

Staff must only use AI systems in accordance with:
- this standard, including the AI Ethics Principles.
- policy frameworks and any local policies and processes.
- any applicable governing laws.

In particular, staff must:
- only use AI systems that have been assessed and approved for use.
- never use AI in a way that could negatively impact a person's fundamental rights, safety or autonomy.
- only use and release WA health system information in AI systems as authorised by the Data Custodian.
- never enter information, or use AI-produced information, that could result in breaches of privacy, copyright or intellectual property (IP) rights.
- if personal information is involved, privacy must be safeguarded in line with legislation and using secure data protection techniques.
- disclose that an AI system has or will be used if the results have potential to impact people, government/business decisions or public opinion.
- avoid over-reliance on AI. Staff remain accountable and responsible for making final decisions. AI tools should support and add value to work, rather than replace.
- always scrutinise outputs for inaccuracies, bias or "hallucinations", and report any issues of concern.
- be aware of any liability risks if the AI-use contravenes contracts or terms of use, results in regulatory breaches, harm, or inaccurate or inequitable outputs.
- complete any system-specific or mandatory training before using the system, where the training is available.
- retain records created by the AI system in accordance with *State Records Act 2000*.
- understand the limitations and risks of using Generative AI. Staff should refer to the following for guidance:
  - Interim guidance on government use of public generative AI tools
  - Generative AI Tools for Internal Government Use
  - Large Language Models

6.2 Clinical Uses of AI

In addition to the above, when using AI systems for clinical purposes, staff must:
- only use AI systems approved via a relevant clinical governance body.

- only use AI systems designed for the relevant clinical purpose and trained using suitable clinical data that is representative of the Western Australian population.
- implement clinical safety and quality policies and guidelines, including processes for disclosure of AI-use and informed consent.
- understand the specific risks related to the system and use-case, mitigate the risks (including usage under the right conditions), continually monitor for errors or bias, and report performance issues for investigation.
- ensure the final decision-making (eg. a diagnosis, recommended treatment or confirming consultation records) is undertaken by a qualified clinician who carefully reviews the outputs before confirming.

7. WA Health Entity Requirements

7.1 Strategic Alignment

The use of AI systems must align with the WA health system's strategic and sustainable health priorities, as outlined in the WA Health Digital Strategy and Sustainable Health Review. Key strategic themes include:

- **Patient-experience**: investment in AI is optimised to the benefit of patients and the Western Australian community.
- **Quality, safety and population health**: the use of AI systems meets clinical safety and quality standards, and enables priority areas of healthcare to be addressed.
- **Staff engagement**: the staff and organisation are supported to develop capability, capacity and maturity to appropriately implement, use and interpret AI systems.
- **Cost and waste reduction**: Innovate for performance and sustainability, recognise the total costs over the life of a system. Actively seek opportunities for health-wide collaboration.

The WA Health AI Working Group (HAIWG) has been established to help foster collaboration and identify significant and strategic opportunities to use AI across WA health entities. The HAIWG will report through to the Architecture Review Committee (ARC).

7.2 Governance

WA health entities must:

- comply with the WA Government AI Policy and Assurance Framework.
- identify appropriate accountability and responsibilities to ensure responsible use and adoption of AI in their entity (see also: AI Ethics Principle 8: Accountability). This must include an AI Accountable Officer with overall responsibility for the organisation's AI strategy, to ensure the adoption of AI aligns with ethics principles, strategic objectives, policy frameworks, governing law and the external environment.
- ensure AI governance processes are consistent with existing governance frameworks, including clinical safety and quality, ethics, digital health, ICT, information and research governance frameworks.

- ensure sufficient expertise is available to assist governance bodies and authorised officers who will be responsible for reviewing or approving AI proposals.
- maintain currency of knowledge of principles, objectives, policy, law and changing technology and risk environment. Any required amendments to local policy, procedures and contract arrangements should be identified and implemented.
- Governance arrangements may build on existing frameworks by adding AI expertise to existing governance groups as applicable.

7.3 Workforce Capability

WA health entities must:

- identify training and skills needed within their workforce to support and deliver services based on AI systems when needed. Training areas may include:
    - general understanding of AI systems.
    - the responsible, ethical and legal use of AI systems.
    - the skills required to interact with and interpret AI-generated insights.
    - the training or qualifications required to undertake specialised roles such as clinical validation or data management.
    - capability in areas with responsibility for governance (eg. clinical governance, ethical review or local ICT governance or ICT support).
    - knowledge to identify and respond to risks associated with AI systems.
    - knowledge to identify and respond to changes in the regulatory environment.

7.4 Risk and Assurance

The use of an AI system requires WA health entities to undertake the DGov self-assessment (refer to WA Government AI Assurance Framework), unless a DGov exception applies. WA health entities must ensure the results of this self-assessment are:

- approved by a suitable Authorised Officer.
- provided to any overseeing governance bodies, e.g. digital health governance, clinical governance, research governance.
- transferred to an appropriate risk system or register for ongoing management.

In addition, WA health entities must:

- document plans for ongoing monitoring and evaluation, using external auditors and best practice standards as necessary to address the level of risk and complexity.
- ensure there are channels available for users to communicate feedback or concerns, and users are aware WA health system incident management policies and processes (such as MP 0122/19 Clinical Incident Management Policy and MP 0135/20 Information Breach Policy).
- identify ongoing accountabilities and responsibilities.
- identify an appropriate risk system or register to ensure any risks are managed throughout the life of the AI system. Consider including residual risks identified from the WA Government AI Assurance Framework and ICT patient safety risk assessments.
- seek legal advice on any AI projects where there are compliance concerns.

7.5 Contract Management

When contracting for ICT, digital health systems and medical technology, WA health entities must:

- specify in writing that the vendor:
    - declares the nature of any AI in their products and services.
    - notifies the contract manager if any new or updated AI-based feature is released in products they are supplying.
    - allows the customer to opt out of AI features.
    - provides assurance of ongoing adherence to WA health entities' requirements, particularly in relation to:
        - any AI specifications provided during the procurement process (note: HSS Customer Engagement Team can provide a standard set of "Non-Functional Requirements")
        - digital security as per MP 0067/17 Information Security Policy
        - information governance as per MP 0015/16 Information Access Use & Disclosure Policy.
        - clarify liabilities and indemnities, with particular consideration of any proposed departures from standard terms and conditions.

8. AI Ethics Principles

The AI Ethics Principles set out in the Australia's AI Ethics Framework and WA Government Artificial Intelligence Policy are closely aligned and provide a useful guide for people using or implementing AI systems. WA health entities must apply the AI Ethics Principles when using or implementing AI systems. The following section describes how the principles must be applied in the WA health system.

AI Ethics Principles

1. Human, social and environmental wellbeing
2. Human-centred values
3. Fairness
4. Privacy protection and security
5. Reliability and safety
6. Transparency and explainability
7. Contestability
8. Accountability

Principle 1: Human, Social and Environmental Wellbeing

This principle states that: "throughout their lifecycle, AI systems should benefit individuals, communities, and where applicable, the environment".

WA health entities must ensure that the AI system:

- is used for the benefit of patients, staff or the public and does not cause harm. The benefits of the AI system must outweigh the risks. Any risks and negative impacts are identified and manageable.

- has documented purpose, benefits, efficacy, datasets, flaws and limitations, and these are reported to authorised officers and governance bodies as required.
- includes timely input from stakeholders (such as clinicians, consumers and community members, subject matter experts and legal advisors) to understand any potential harms and benefits, ensure trustworthiness, and enable those impacted to shape the system design and use. Key stakeholders are involved in the assessment, planning and design of systems.
- is never designed or used in a way that involves deception, unfair manipulation, surveillance (except where legally permissible), or failure to disclose a true and accurate purpose.

Principle 2: Human-Centred Values

This principle states that: "throughout their lifecycle, AI systems must respect human rights, dignity, diversity and the autonomy of individuals".

WA health entities must ensure:

- the AI system is not used to make unilateral decisions that impact patients or citizens, or their human rights.
- humans always remain in control of health-care systems and clinical decisions. AI assists, complements and empowers clinicians, who make final decisions.
- the nature of any AI use is disclosed so that patients and citizens are informed and can continue to exercise their capacity for self-determination (see also Principle 6. Transparency and Explainability).
- ethical review of the proposal is undertaken by appropriate governance bodies, such as Clinical Ethics Committees and Human Research Ethics Committees.
- compliance with:
    - Australia's Constitutional and legislated human rights protections
    - Australia's international human rights obligations
    - WA Public Sector Code of Ethics and MP 0124/19 Code of Conduct Policy
    - Professional standards of ethical practice, such as National Practitioner Boards Codes of Conduct.

Principle 3: Fairness

This principle states that: "throughout their lifecycle, AI systems should be inclusive and accessible, and should not involve or result in unfair discrimination against individuals, communities or groups".

WA health entities must ensure:

- AI systems enable fair and equitable access to healthcare and government services, and it does not exacerbate existing disparities in access, such as those related to race, sex, gender or socioeconomic status.
- staff working with AI systems are adequately trained or qualified to monitor and manage the possibility of bias within:
    - **AI algorithms** (including in self-developed models): Algorithms must be impartial to prevent bias against individuals or groups based on race, sex, gender, religion, culture, language, ethnicity or any other form of discrimination.
    - **data used to train AI models**: Datasets need to be appropriate for the WA health context and use case, including WA ethical, societal, cultural and legal context.
    - **AI-produced outputs**: Outputs needs to be continuously monitored for compliance with anti-discrimination laws and so that they do not disproportionately impact certain demographic groups.
- staff members implementing AI systems are mindful of the potential harms/negative impacts of racial and gender biases and put in place strategies to mitigate the unwanted bias/discrimination within AI systems. Expectations for the equitable treatment of people within the WA health system are outlined in:
    - MP 0185/24 Health Equity Impact Statement and Declaration Policy
    - MP 0160/21 Aboriginal Health Impact Statement and Declaration Policy
    - NSQHS Standards User Guide for Aboriginal and Torres Strait Islander Health
- where the AI is used to listen to staff, patients' or customers' speech, that comprehensive testing is demonstrated to account for a range of accents/languages as necessary to ensure accurate functioning.
- staff must refer to Principle 6: Transparency and explainability to ensure transparency in the use of AI where language barriers may be present.
- staff must also be aware of the National Agreement on Closing the Gap which outlines the importance of the transparency and accountability of Aboriginal data, access, sharing and control.

Principle 4: Privacy Protection and Security

This principle states that: "throughout their lifecycle, AI systems should respect and uphold privacy rights and ensure the security and protection of data".

Privacy

WA health entities must ensure privacy and appropriate use of personal and health information when using AI systems. This includes:

- only collecting, using and disclosing information in accordance with MP 0015/16 Information Access, Use and Disclosure Policy and *Privacy and Responsible Information Sharing Act 2024*.

- not entering Official Information or Official: Sensitive information (including personal and health information) into public Generative AI systems that integrate with the internet, unless there is specific approval to release this information for public use and reproduction.
- where personal information is involved, always using data protection techniques such as:
    - data anonymisation and deidentification
    - synthetic data
    - encryption
    - secure aggregation.
- if using a vendor product, the vendor's arrangements for collection, access, use, storage and transfer of WA health's data must be disclosed to and agreed by the relevant Information Custodian or Steward.
- if an automated decision-making process is involved, uses personal information and makes significant decisions about individuals, WA health entities must comply with "Information Privacy Principle (IPP) 10 – Automated Decision Making" of the *Privacy and Responsible Information Sharing Act 2024*.

Security

AI systems are critical organisational assets, often storing and processing vast amounts of data. Security breaches in AI systems may result in serious consequences for patient safety, privacy and intellectual property (IP) control.

WA health entities must ensure:

- AI systems, including vendor-procured systems, undergo a security risk assessment and are protected in line with:
    - WA Government Cyber Security Policy
    - MP 0067/17 Information Security Policy
- a cloud service assessment is completed if the AI system will be hosted on cloud-based infrastructure (refer to MP 0120/20 Cloud Policy).
- relevant staff maintain up-to-date awareness of the latest security threats to AI systems and apply recommended updates and protections. Some specific challenges for AI include:
    - theft of information or algorithms.
    - data poisoning of an AI model's training data so that the AI model learns incorrect patterns to produce inaccurate, biased or malicious outputs.
    - tampering with the performance of algorithms to hijack the system or output or cause the AI system to produce incorrect outputs.
    - reverse engineering AI algorithms and obtaining identifying information of patients whose data were used in developing the AI.

Principle 5: Reliability and Safety

This principle states that: "throughout their lifecycle, AI systems should reliably operate in accordance with their intended purpose".

Reliability

Prior to implementation, WA health entities must ensure the AI system is:

- trained on data that is fit for purpose.
- tested with local, ethical and de-identified or synthetic data.
- piloted to verify correct operation, if the residual risk is moderate or higher.
- evaluated using high quality standards of evidence before implementation.
- is used under appropriate conditions by appropriately trained or qualified people.
- accompanied by application-specific guidance or training to communicate the approved use case/s, and any risks, limitations or mitigations.

Throughout its operation, WA health entities must ensure there are:

- documented monitoring and evaluation plans in place to:
    - verify the AI system continues to meet its acceptance criteria.
    - detects any performance shifts and incorrect or biased results.
- regular independent audits if the level of risk warrants a comprehensive audit plan.
- clear avenues for staff members to report risks or notify issues and incidents.

For complex or high-risk implementations, WA health entities must refer to an established AI risk management framework, for example:

- NIST: Artificial Intelligence Risk Management Framework: Generative Artificial Intelligence Profile (NIST AI 600-1) (nist.gov)
- NIST: Artificial Intelligence Risk Management Framework (AI RMF 1.0) (nist.gov)
- AS/ISO IEC 23894-2023 - Information technology - Artificial intelligence - Guidance on risk management

Safety

In addition to the above mechanisms for ensuring reliability, where AI applications will be used in health care settings, WA health entities must ensure:

- throughout design, implementation and oversight:
    - suitable clinicians are involved as key stakeholders.
    - the AI system continues to be deployed under the supervision of the responsible Clinical Executive.
    - the clinician must be the final decision-maker, taking on the responsibility of the decision and assessed risk.
    - ensuring staff members hold the appropriate qualifications and credentials to competently use the technology; and that its use is within their scope of clinical practice.
    - the AI system has been through a process of rigorous and multi-modal clinical validation of its algorithms before deployment in healthcare settings, to include evaluation of discrimination accuracy, calibration accuracy, and both internal and external testing.
- there is an auditable plan for how clinical safety will be assessed and managed on an ongoing basis. This must include:
    - routine methods of auditing, frequency and oversight responsibility
    - processes for notifying patient safety concerns and events.
    - governance body actively monitoring clinical safety issues.

The Clinical Governance, Safety and Quality Policy Framework sets out the broader scope of clinical governance across WA health. If the AI system is to be used in a clinical setting, the Applicant must consult with their Safety and Quality area for assessment and advice, and comply with all standards, regulations, codes, guidelines and scopes of practice applicable, including the ACSQHC's Clinical AI Usage Guidance .

If the intention is to implement a new or significantly extended health technology that is high risk in terms of patient safety or has statewide planning implications, staff must refer to MP 0072/17 Health Technology Governance Policy.

TGA Regulation

AI systems which are intended to be used for a medical purpose may require approval by the Therapeutic Goods Administration (TGA) (software as a medical device regulation). Medical devices are broadly defined as products intended by their manufacturer for use in humans in connection with:

- diagnosis, prevention, monitoring, prediction, prognosis, or treatment of a disease, injury, or disability,
- alleviation of, or compensation for, an injury or disability,
- investigation of the anatomy or of a physiological process, and
- control or support of conception.

When procuring medical devices in Australia, it must be confirmed with the sponsor of the goods that the product is either included in the Australian Register of Therapeutic Goods (ARTG), or is an 'exempt' medical device.

Patient Safety Risks

If the system has potential to impact patients, directly or indirectly, an ICT Patient Safety Risk Assessment and Report must be used to capture and manage these risks. ICT Patient Safety requires systems to provide the correct information for the correct person, at the correct time and place to the correct clinician. Some potential hazards include:

- staff misunderstanding limitations of outputs and misinterpreting meaning.
- staff being unaware their AI system can evolve and change outputs over time.
- over-reliance on AI systems (eg. decision-making, not decision support only).
- AI systems that are:
    - poorly programmed with unsafe or biased algorithms.
    - trained with inadequate or unrepresentative data (e.g. biased population data, dated data).
    - vulnerable to hacking.
    - used in an inappropriate setting or context, which may result in inaccurate responses now or skew the system's responses over time.
    - providing incorrect responses or analyses (possibly through "hallucination").
    - implemented without ongoing validation, monitoring or governance.
    - replacing valuable clinician / consumer relationship.

Principle 6: Transparency and explainability

This principle states that: “there should be transparency and responsible disclosure so people can understand when they are being significantly impacted by AI and can find out when an AI system is engaging with them”.

WA health entities must:

- only employ AI models that can be explained and is understandable to developers, healthcare professionals, patients, users and regulators. Avoid using AI tools where the type of tool and how it has been trained and proven to work has not been disclosed.
- always be open and transparent when using AI systems that could significantly impact a person, community, group or the environment. Transparency includes any material risks and benefits so that patients and other persons can make informed decisions about their use. This information should be provided to end users, patients and other responsible parties to ensure all stakeholders can understand how the AI algorithm makes decisions.
- seek a patient’s consent to AI-use unless an ‘exception’ applies (refer to MP 0175/22 Consent to Treatment Policy). Patients should have the ability to opt-out.
- build trust in WA health system’s information by disclosing, at a minimum, when Generative AI tools are being used to:
    - inform government activities / decisions.
    - generate official briefings, corporate communications.
    - enable autonomous decision-making.

  Generative AI disclosure statements must include:
    - how the AI contributed to the content (prompts entered, resources used)
    - the human oversight or editing that occurred after the AI generated content.
    - version and type of model (eg. ChatGPT 3.5)
- identify if there are potential language or cultural barriers in ensuring transparency in the use of an AI system, if so, refer staff to MP 0051/17 Language Services Policy and work in partnership with Culturally and Linguistically Diverse (CALD) and Aboriginal communities to evaluate and document how the appropriate level of communication and transparency can be identified, established and implemented.
- comply with IPP 10 of the *Privacy and Responsible Information Sharing Act 2024*, which requires WA health entities to:
    - notify the individual that an automated decision-making process has been employed in making the decision.
    - on request, give the individual information about how the automated decision making is employed in making decisions, and
    - provide a process by which the individual can request human intervention in relation to the decision.

Principle 7: Contestability

This principle states that: “when an AI system significantly impacts a person, community, group or environment, there should be a timely process to allow people to challenge the use or outcomes of the AI system”.

WA health entities must:

- provide patients and citizens with access to an efficient and transparent review mechanism if there are questions about the use of data or AI-informed outcomes. This must include sufficient access to and understanding of the algorithm and inferences drawn. The review mechanism must have human oversight.
- uphold the patient’s right to make informed decisions about their health care and provide alternative approaches to care where consent is not given or has been withdrawn. This requires meaningful information about the proposed treatment to be provided to the patient, including details of the benefits and material risks specific to that patient.
- refer to the *Privacy and Responsible Information Sharing Act 2024* for obligations around disclosure and human review if the system involves personal information, impacts humans and will employ automated decision-making.

Principle 8: Accountability

This principle states that: “AI systems should be subject to human oversight, so that people can intervene if they believe that an AI system is making a decision that is unsafe, unfair, or biased”.

Roles and Responsibilities

WA health entities must ensure AI systems are overseen by a clear governance structure with defined roles and responsibilities, accountability and liability, where relevant. Some of the primary roles to identify are:

- **AI Accountable Officer:** an Executive whose role is to oversee AI strategy and governance in the entity.
- **Executive Sponsor**: an internal officer with overall accountability for ensuring the AI system meets requirements. If the system impacts patients, the Executive Sponsor must be a **Clinical Executive**.
- **Accountable Supplier**: This is the Executive overseeing development of the system (whether developed in-house or by a vendor).
- **Information Custodian**: Person responsible for data governance of an information asset.
- **Authorised Officer**: Employees with authority afforded to them under the WA health entity’s Authorisations and Delegations Schedule.
- **Technical Oversight**: An executive technical officer eg HSP CIO or equivalent.

- **AI Model Validator**: A person who evaluates the performance of the AI system to ensure explainability and robustness.
- **Independent AI Auditor**: Organisation or entity who audits or assesses the system's conformance with policies, standards or legal requirements.
- **Clinician**: Where the AI application is used in the context of clinical decision-making, a clinician must be the final decision-maker, taking on the responsibility of the decision and assessed risk.
- **Designers, developers, data engineers, analysts and scientists**: Continuously, systematically and transparently assess AI applications as part of their function and in accordance with documented monitoring, testing and evaluation plans.
- **Users and end users:** any persons using the working AI model must ensure their usage is in accordance with the approved use-case, mandatory policies and laws; they have undertaken any required training; they continuously monitor the quality and accuracy of the system's outputs; and they raise incidents or risks as per their organisation's reporting processes.

Records Management

WA health entities must:

- ensure all records created by or through the use of AI are kept in accordance with the *State Records Act 2000.*
- ensure records of the use of AI in business activities (including design, testing, implementation, system evaluation and decommissioning) are retained in the WA health entity's approved recordkeeping system.
- refer to the State Records Office Artificial Intelligence Record Keeping advice for using AI tools to manage records.

9. Definitions

Term	Definition	
Artificial Intelligence (AI)	An interdisciplinary field, dealing with models and systems for the performance of functions generally associated with human intelligence, such as reasoning and learning. In WA, the scope of AI is wide and includes automated decision making and data driven tools.	
Artificial Intelligence (AI) System	An engineered system that generates predictive outputs such as content, forecasts, recommendations, or decisions for a given set of human defined objectives or parameters without explicit programming. AI systems are designed to operate with varying levels of automation.	
AI Terms	Computer Vision	Capability of a functional unit to acquire, process and interpret data representing images or video.

	Generative AI	Uses machine learning to generate new content, such as text, images and websites.
	Large Language Models	A type of machine learning (ML) model that can perform a variety of natural language processing (NLP) tasks, such as generating and classifying text, answering questions in a conversational manner, and translating text from one language to another.
	Machine learning (ML) *ML subcategories* • Neural Networks • Deep Learning	Mathematical construct that generates an inference or prediction based on input data or information. • Network of one or more layers of neurons connected by weighted links with adjustable weights, which takes input data and produces an output. • An approach to creating rich hierarchical representations through the training of neural networks with many hidden layers.
	Natural Language Processing (NLP)	Information processing based upon natural language understanding or natural language generation.
	Robotics • Robots • Robotic Process Automation (RPA)	Science and practice of designing, manufacturing and applying robots. Automation system with actuators that performs intended tasks the physical world, by means of sensing its environment and a software control system. An application of technology aimed at automating business processes and governed by business logic and structured inputs. Using RPA tools, an organisation can configure software or a 'robot' to capture and interpret applications for processing a transaction, manipulating data, triggering responses or communicating with other digital systems.
Automated decision-making process	An automated decision-making process is a process under which – • a decision is made by an automated system without the involvement of any individual, or	

	• the making of a decision is materially assisted by an automated system.
Authorised Officer	Employees with authority afforded to them under the WA health entity's Authorisations and Delegations Schedule.
Harm	Any adverse effects experienced by an individual (or organisation) including those which are socially, physically or financially damaging.
Health Information	Has the meaning given in the *Health Services Act 2016,* section 213 as: (a) information, or an opinion, that is also personal information, about: (i) the health (at any time) of an individual; or (ii) a disability (at any time) of an individual; or (iii) an individual's expressed wishes about the future provision of health services to the individual; or (iv) a health service provided, or to be provided, to an individual; or (b) other personal information collected to provide, or in providing, a health service.
Information Custodian	Implements policy on behalf of the Steward and has the delegation authority for granting access, use and disclosure of information from Information Assets in line with legislation and policy.
Official Information	Has the meaning provided in MP 0146/20 Information Classification Policy: Information created or processed in the WA health system as part of the business of Government including Department of State, System Manager and Health Service Provider functions.
Official: Sensitive Information	Has the meaning provided in MP 0146/20 Information Classification Policy: Official information that could result in damage to individuals, organisations or government if released.
Personal Information	Has the meaning given in the *Freedom of Information Act 1992* in the Glossary clause 1: Means information or an opinion, whether true or not, and whether recorded in a material form or not, about an individual, whether living or dead — a) whose identity is apparent or can reasonably be ascertained from the information or opinion; or

	b) who can be identified by reference to an identification number or other identifying particular, such as a fingerprint, retina print or body sample.
Use Case	A use case is a software and system engineering term that describes how a user uses a system to accomplish a particular goal. A use case acts as a software modelling technique that defines the features to be implemented and the resolution of any errors that may be encountered.
WA health entities	WA health entities include: a) Health Service Providers as established by an order made under section 32(1)(b) of the *Health Services Act 2016*. b) Department of Health as an administrative division of the State of Western Australia pursuant to section 35 of the *Public Sector Management Act 1994*.
WA health system	The WA health system is comprised of: i. the Department ii. Health Service Providers (North Metropolitan Health Service, South Metropolitan Health Service, Child and Adolescent Health Service, WA Country Health Service, East Metropolitan Health Service, PathWest Laboratory Medicine WA, Quadriplegic Centre and Health Support Services); and iii. contracted health entities, to the extent they provide health services to the State.

10. Document Control

Version	Approved by	Published date	Review date	Amendment(s)
1.0	Shaun Walsh A/Executive Director Digital Health	10 September 2025	March 2027	Original version

11. Enquiries

Enquiries relating to this policy may be directed to:
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Directorate: Digital Health
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Appendix A: Clinical AI Proposal – Checklist

Questions	Checklist
1. Is this proposal within the Scope and Definition of MP 0193/25 AI policy?	Refer to Section 4. Scope and Section 5. What is AI? ☐ If yes, go to the next step.
2. Does this comply with TGA regulations?	Confirm this either: ☐ Has TGA approval (see: Australian Register of Therapeutic Goods) OR ☐ Is not regulated by the TGA.
3. Is this a production tool or research tool?	☐ If Production, seek HSP Clinical Governance / Health Technology Governance approval. ☐ If Research, seek HSP Research Governance approval. Provide to the relevant body: ☐ Completed WA Gov AI Assurance Framework ☐ Completed Cloud Service Assessment ☐ Completed Patient Safety Risk Assessment ☐ Plan for adherence to Clinical AI Usage Guidance ☐ Standard Pre-CAR/Digital Demand Item form ☐ Any Local AI Governance documentation **Examples of completed templates will be provided on AI and Clinical Innovation HealthPoint site when available.*
4. Will this tool use Official, Official Sensitive or personal information?	☐ Obtain Information Governance approval
5. Does this impact people from Aboriginal or CaLD backgrounds or living in lower socioeconomic conditions?	If yes, confirm compliance with: ☐ MP 0160/21 Aboriginal Health Impact Statement and Declaration Policy ☐ MP 0185/24 Health Equity Impact Statement and Declaration Policy
6. If approved by the governance body:	☐ Submit Pre-CAR to local HSP digital demand governance process. ☐ Also email the Pre-CAR to Office of Digital Health AI and Clinical Innovation mailbox.
7. WA AI Advisory Board review	☐ In some cases, the completed WA Gov AI Assurance Framework will need to be reviewed by the WA AI Advisory Board. Refer to the WA Gov AI Policy and Assurance Framework for conditions.

Appendix B: Additional Resources

Australian Government

- WA: Office of Digital Government – WA Artificial Intelligence Policy
- WA: Office of Digital Government – WA AI Assurance Framework
- Australian Government Policy for the Responsible Use of AI in Government | 2024
- National framework for the assurance of artificial intelligence in government | 2024
- Australian Government Voluntary AI Safety Standard | 2024
- Australia's Artificial Intelligence Ethics Framework | 2019
- Safe and responsible AI in Australia Consultation | 2023
- Adoption of Artificial Intelligence in the Public Sector | Aust Govt Architecture
- Interim Guidance on Government Use of Public Generative AI tools | Nov 2023

Australian AI in Health

- Australian Alliance for AI in Health Roadmap | 2021
- Australian Commission on Safety and Quality in Health Care (prepared for) | Literature Review and Environmental Scan Report I AI Implementation in Hospitals: Legislation, Policy, Guidelines and Principles, Evidence about Quality and Safety | 2024
- e-Health safety | Australian Commission on Safety and Quality in Health Care
- Ethical Principles for AI in Medicine | RANZCR (College of Radiology) | Sept 2023
- Artificial intelligence in primary care | RACGP (College of GPs) | Updated April 2024
- RACGP - Artificial intelligence (AI) scribes
- Artificial Intelligence in Healthcare | Australian Medical Association (ama.com.au)
- Therapeutic Goods Administration: Artificial Intelligence (AI) and medical device software
- Therapeutic Goods Administration: Medical device software regulation
- Therapeutic Goods Act 1989 - SECT 41BD What is a medical device?

Other States / Jurisdictions

- NSW: Artificial Intelligence Assessment Framework | Digital NSW
- NSW: Artificial Intelligence Living Evidence | Agency for Clinical Innovation
    - Clinical applications of artificial intelligence
    - AI: automating indirect clinical tasks and administration
    - AI system implementation issues and risk mitigation
- VIC: Generative AI and Local Governance Models | Health Service Guidance
- VIC: Advisory: Health Service Use of Unregulated Artificial Intelligence | July 2023
- VIC: Use of Microsoft 365 Copilot in the Victorian public sector

International

- EU AI Act: High-level summary of the AI Act | EU Artificial Intelligence Act | 2024
- NHS UK: "AI: How to get it right report summary" | 2019
- NHS UK: "Buyer's Guide to AI in Health and Care" | 2020
- OECD Legal Instrument: Recommendation of the Council on Artificial Intelligence
- Singapore Ministry of Health: AI in Healthcare Guidelines | 2021
- The Seoul Declaration by countries attending the AI Seoul Summit, 21-22 May 2024
- The Bletchley Declaration by Countries Attending the AI Safety Summit, 1–2 Nov 2023
- World Health Organisation: Ethics and Governance of Artificial Intelligence for Health

Risk Management Frameworks

- NIST: AI Risk Management Framework
- AS/ISO IEC 42001-2023 - Information technology - Artificial intelligence - Management system
- AS/ISO IEC 23894-2023 - Information technology - Artificial intelligence - Guidance on risk management
- AS/ISO IEC 38507-2022 - Information technology - Governance of IT - Governance implications of the use of artificial intelligence by organizations
- ISO/IEC 22989:2022 Information technology - Artificial intelligence - Artificial intelligence concepts and terminology

Security

- ACSC: Engaging with Artificial Intelligence | Cyber.gov.au
- ACSC: Deploying AI Systems Securely | Cyber.gov.au
- Guidelines for secure AI system development - NCSC.GOV.UK
- NIST: AI 100-2 E2023, Adversarial Machine Learning: A Taxonomy and Terminology of Attacks and Mitigations

Consumer and Citizen

- Medical Journal of Australia Volume 220, Issue 8 May 2024: How should artificial intelligence be used in Australian health care? Recommendations from a citizens' jury (wiley.com)
- Hai Jin Park, Patient perspectives on informed consent for medical AI: A web-based experiment - 2024 (sagepub.com)

Data Protection Legislation

- *Health Services Act 2016*
- *Public Health Act 2016*
- *Privacy and Responsible Information Sharing Act 2024*
- *State Records Act 2000*

Human Rights Legislation

- *Australian Human Rights Commission Act 1986*
- *Age Discrimination Act 2004*
- *Disability Discrimination Act 1992*
- *Equal Opportunity Act 1984*
- *Racial Discrimination Act 1975*
- *Sex Discrimination Act 1984*

Learning Resources

- Artificial Intelligence - CSIRO
- Artificial intelligence | The Alan Turing Institute
- Australian Health Practitioner Regulation Agency - Meeting your professional obligations when using Artificial Intelligence in healthcare
- CSIRO's Data61 - YouTube
- Resources | Ai Health Alliance

This document can be made available in alternative formats on request for a person with a disability.