Policy 3.7

POLICY TITLE:	ARTIFICIAL INTELLIGENCE	POLICY #		REVIEW DATES	
Topic Area: INFORMATION MANAGEMENT		**ISSUED BY:** Chief Executive Officer			
Applies to: Lakeshore Regional Entity (LRE) employees and Contractors					
Developed and Maintained by: Chief Information Officer (CIO)		**APPROVED BY:** Chief Executive Officer			
Supersedes: N/A		**Effective Date:** 3/28/2025		**Revised Date:**	

I. PURPOSE

To establish guidelines for the use of any Artificial Intelligence tool or technology ("AI Tool") (i) by Lakeshore Regional Entity employees or Contractors ("LRE Staff") and (ii) in a manner that is safe, effective and consistent with applicable legal requirements and information privacy and security protocols.

II. POLICY

Any AI Tool to be used within LRE, by LRE Staff in the performance of services for or on behalf of LRE, or using the equipment, resources or information of LRE, must be approved in writing by the CIO or his/her designee prior to its purchase, installation, implementation, or use. All approved AI Tools shall be purchased, installed, implemented and used in accordance with this Policy, all other applicable LRE policies and procedures, and all applicable laws and regulations. Following implementation of an approved AI Tool, LRE will continue to monitor such AI Tools for safety, effectiveness, and compliance.

LRE will implement the following to ensure the ethical and responsible use of AI Tools:

- **Data governance:** LRE will define the roles and responsibilities of those involved in the development, use, and oversight of AI tools used to collect, store, and process data. LRE is setting forth the ethical principles described below that will guide the use of AI Tools in the business, and include procedures for data collection, storage, and processing.

- **Due diligence on AI Tools:** Before deploying an AI Tool, LRE will conduct due diligence to ensure that the tool is safe, effective, and aligned with its ethical principles. This due diligence should include reviewing the tool's data collection and usage practices, its potential for bias, and its compliance with applicable laws and regulations.

- **Technical Controls:** LRE will ensure that effective technical controls are in place to protect the security and privacy of PHI and/or other confidential data, including when such data is used by AI Tools. These controls will include but will not be limited to:

   o Data encryption, for data both at rest and in transit.

- o Access controls including strong passwords and Multi Factor Authentication (MFA).

CONSIDERATIONS

1. *Identification and Evaluation of AI Technology.* AI Tools must be carefully reviewed and approved in accordance with this Policy prior to purchase, installation, implementation, or use. Initially, the CIO will determine whether the proposed tool uses or includes AI Technology. If it does, the CIO and applicable department leader(s) will then review and analyze the AI Tool for its intended use. If the AI Tool involves the recording or surveillance of individuals, including patients, employees, contractors, providers or visitors, the LRE Compliance Officer will be consulted and involved in the evaluation process.

2. *Implementation of AI Tools.* If an AI Tool is approved, the applicable department leader(s) will, in consultation with the CIO, implement procedures to guide and govern use of the AI Tool as intended and in a manner that complies with all applicable laws, regulations and LRE policies and procedures. The CIO or his/her designee will be responsible for ensuring that approved AI Tools are implemented in accordance with such procedures and for monitoring the use of such AI Tools for continued compliance. If after approval, the AI Tool or its intended use changes, the revised AI Tool and/or intended use shall be re-evaluated in accordance with this Section.

   If concerns arise in the implementation of any AI Tool, the applicable department leader(s) and CIO should work with applicable LRE committees and involved individuals to address the concern.

3. *Use or Disclosure of PHI.* If Protected Health Information will be used, disclosed or accessed through the use of an AI Tool, additional protocols must be implemented to protect the confidentiality and security of such PHI. The CIO shall consult with the Compliance Officer, Privacy and Security Officer(s), Chief Executive Officer, and, where applicable, with legal counsel prior to approval of any such AI Tool (or approval of any additional intended use of an existing approved tool) and in relation to the creation and implementation of any such additional protocols.

   (i) Patient Consent or Notice. Prior to approval, implementation, or use of any AI Tool for use in the care of patients or in a manner that uses or discloses PHI, LRE will determine if patient consent is required and if so, will ensure the patient consent form(s) include reference to the use of the AI Tool. If informed consent is not required, LRE will evaluate whether notice to patients is required or prudent and, if so, the applicable department leader(s) and the Compliance Officer, in consultation with legal counsel, if needed, will work collaboratively to develop an appropriate notification process.

(ii) Medical Record Documentation. If an approved AI Tool, which may include Generative AI, utilizes any recording or surveillance technology, consent or notice will be implemented in accordance with LRE's [Recording & Surveillance] Policy. To the extent AI will be utilized in the generation of documentation included in the patient's medical record, LRE Staff using the AI must comply with all LRE policies applicable to medical record documentation and the timely and accurate completion of medical records. In no event may any LRE Staff utilize AI in the creation of patient medical record documentation without reviewing the record for accuracy and completeness and signing the record in compliance with applicable law and LRE policies. Upon approval of any new AI tool (or approval of any additional intended use of an existing approved tool) and prior to implementation or use of any new AI tool or additional intended use, LRE will update its policies relating to medical record documentation as needed to address the additional use of AI.

4. *Contract Review*. All agreements for the purchase, licensing or use of an AI Tool must be reviewed and approved in accordance with the LRE [Contract Review] Policy and in consultation with the CIO and legal counsel, as appropriate.

5. *Use of AI Technology with Third Parties*. LRE recognizes that AI Technology provided by or used with third parties are increasingly available. LRE Staff should only participate with third party AI Technology in the performance of their job duties if the AI Technology is approved for use by LRE in accordance with this Policy.

6. *Use of AI Technology in Virtual Meetings*. LRE Staff attending meetings sponsored or hosted by third parties must be cognizant of involvement of AI Technology in such meeting and must not disclose PHI or other confidential information in such meeting.

7. *Training on AI Technology*. The LRE CIO or designee will be responsible for training all new LRE *S*taff (as part of employee onboarding) and all existing staff (annually at minimum) regarding awareness of LRE AI policies and procedures. The applicable department leader(s) will be further responsible for training LRE Staff in their respective departments on the appropriate use and approved intended uses of AI Technolog*es, including* protocols and limitations on their use. LRE Staff training/re-training must occur on a regular basis as deemed appropriate by the applicable department leader(s) in consultation with the CIO and Compliance Officer. Such training shall include, without limitation, information (i) regarding the potential risks to data privacy and security, information authenticity, and patient safety; (ii) to assist LRE Staff in recognizing an AI Tool when they encounter one; (iii) explaining LRE acceptable/approved intended uses as well as any limitations and prohibitions on use; (iv) regarding acceptable and unacceptable exposure of intellectual property and proprietary or copyrighted materials to an AI Tool; and (v) on how to report concerns regarding any AI Tool or its use.

III. APPLICABILITY AND RESPONSIBILITY

This Policy applies to all LRE Staff. Any LRE employee who violates this Policy may be subject to disciplinary action up to and including termination of employment. Violation of this Policy by any LRE Contractor may result in disciplinary action up to and including termination of such Contractor's relationship with LRE. Use of any AI Tool to perform unauthorized, malicious or inappropriate actions, or to generate malicious, inappropriate or illegal material, is strictly prohibited and will result in disciplinary action.

IV. MONITORING AND REVIEW

After implementation of an AI Tool (or approval of an additional intended use of an existing approved tool), the applicable department leader(s) in consultation with the CIO will, on a quarterly basis for the first 24 months of use and no less than annually thereafter, review and evaluate the performance of the AI Tool (and staff compliance with approved intended uses) to assess for safety, effectiveness, and compliance. Such review and assessment will be documented, and any identified concerns addressed by the applicable department leader(s), CIO and, if appropriate, the LRE Compliance Officer and/or the Compliance Committee.

V. DEFINITIONS

Artificial Intelligence (AI): The theory and development of computer systems able to perform tasks that normally require human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages.

Generative AI: Artificial intelligence capable of generating text, images, videos, or other data using generative models, often in response to prompts. Generative AI models learn the patterns and structure of their input training data and then generate new data that has similar characteristics.

Protected Health Information (PHI): Protected health information means individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium as defined under the Health Insurance Portability and Accountability Act of 1996, as amended.

Contractor: A person or entity who performs services, functions or activities for or on behalf of LRE whether or not such services, functions or activities involve the use or disclosure of individually identifiable health information.

VI. RELATED POLICIES AND PROCEDURES

A. LRE Information Management Policies and Procedures (including Artificial Intelligence Procedure)
B. LRE Compliance Policies and Procedures
C. LRE Human Resources Policy and Procedures
D. LRE [Recording and Surveillance] Policy

VII. REFERENCES/LEGAL AUTHORITY

A. Health Insurance Portability and Accountability Act of 1996
B. Health Information Technology for Economic and Clinical Health Act of 2009
C. 45 CFR 164.440-414

VIII.   CHANGE LOG

Date of Change	Description of Change	Responsible Party
3/25/2025	NEW POLICY	CIO