Sample Generative AI Policy

PURPOSE:

The purpose of this Policy is to establish guidelines for the implementation of generative artificial intelligence within the Facility or for use by the Facility's employees or contractors to help ensure any such technology advances the Facility's mission and is safe, effective, and complies with legal requirements.

DEFINITIONS:

"Artificial Intelligence" or "AI" is a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. Artificial intelligence systems use machine and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action.

"Generative Artificial Intelligence" or "Generative AI" is the class of AI models that emulate the structure and characteristics of input data in order to generate content such as images, videos, audits, text, or other digital content.

"Generative AI Technology" is defined as any Generative AI tools and technology systems that deploy one or more Generative AI tools.

"Patient Care Decision Support Tool" is defined as any automated or non-automated tool, mechanism, method, technology, or combination thereof used by the Facility to support clinical decision-making.

POLICY:

Any Generative AI Technology proposed for use within the Facility or by the Facility's employees or contractors in the performance of services for, on behalf of, or using the resources or information of the Facility, including protected health information of the Facility's patients or other confidential, sensitive or proprietary information, must be approved by the Facility prior to its use. Any Generative AI Technology approved for use within the Facility will be implemented in accordance with this Policy, other relevant Facility policies, and any laws and regulations applicable to the Generative AI Technology or its use by the Facility. After implementation, Generative AI Technology will continue to be monitored by the Facility in accordance with this Policy.

PROCEDURES:

1. **Identification of Generative AI Technology**. Prior to the purchase, implementation or use of any technology, the CTO will determine whether the technology uses or includes Generative AI Technology. If the technology uses or includes Generative AI Technology, the Generative AI Technology will not be purchased or implemented until it has

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been evaluated for its intended use as outlined in Section 2. This applies to any Generative AI Technology an employee or contractor desires to utilize in connection with the performance of services for, or on behalf of the Facility, or using the resources or information of Facility, including protected health information of the Facility's patients and other confidential, sensitive or proprietary information.

2. **Evaluation of Generative AI Technology for Intended Use**. Prior to implementing any Generative AI Technology, the Facility will ensure the Generative AI Technology has been evaluated by the appropriate individuals internally and found to be effective for its intended use. Such evaluation will include, but not necessarily be limited to, the following:

(a)   If the Generative AI Technology will be used in the patient care setting or to deliver patient care, the Facility's Patient Safety & Quality Improvement Committee ("QI Committee") must review and approve the Generative AI Technology for its intended use within or by the Facility to help ensure the technology will not compromise patient safety or quality. The QI Committee may request and rely on input and information from other individuals and third parties, including the intended users of the technology.   If the QI Committee approves the intended use, it will work with the applicable Department leader(s), the Compliance Committee, the CTO, and intended users to implement appropriate protocols to help ensure the Generative AI Technology does not jeopardize patient safety or quality.

(b)   If the Generative AI Technology will be used in the billing or coding of items or services provided by the Facility, the Finance Committee must review and approve the Generative AI Technology for its intended use to help ensure the use of the technology will not jeopardize the accuracy of claims or result in overpayments to the Facility. If the Finance Committee approves the intended use, it will work with the applicable Department leader(s), the Compliance Committee, the CTO, and intended users to implement appropriate protocols to help ensure the Generative AI Technology does not jeopardize the accuracy of claims, result in overpayments to the Facility, or create other compliance issues.

(c)   If the Generative AI Technology will be utilized for an employment-related purpose, the Facility's Executive Committee must review and approve the Generative AI Technology for its intended use, including consulting with the Facility's legal counsel to ensure it may be used in an employment-context as intended by the Facility. If the Executive Committee approves the intended use, it will work with the Vice President of Human Resources, the CTO, and the Facility's legal counsel, as needed, to ensure the Generative AI Technology as utilized by the Facility complies with all applicable employment laws and regulations.

(d)   For all other Generative AI Technology, the CTO and applicable Department leader(s) must review and approve the Generative AI Technology for its intended use and if approved, implement appropriate protocols to govern its use.

(e)   If the Generative AI Technology relies on recordings or surveillance of individuals, including patients, employees, contractors, providers, and visitors, the Facility's Privacy & Security Officers will participate in the review process and provide input to the relevant decision-makers.

(f)   In the evaluation of Generative AI Technologies, the applicable Committee and/or CTO and applicable Department leader(s) will consider, as part of its analysis, how the Generative AI Technology addresses and attempts to limit or avoid the potential for bias, including identifying the specific patient, employee or other population the Facility intends to utilize the Generative AI Technology for, risks associated with potential bias, and how those risks will be appropriately mitigated by the Facility.

If after approval, the Generative AI Technology or its intended use within the Facility changes, the revised technology and/or intended use should be re-evaluated in accordance with this Section.

The CTO will maintain a list of all Generative AI Technology approved for use within the Facility.

3.   **Additional Provisions Applicable to Patient Care Decision Support Tools**. The QI Committee must evaluate and make a determination of whether any Patient Care Decision Support Tool uses input variables that measure race, color, national origin, sex, age, or disability. If the QI Committee determines it does, then the specific measures used will be documented and the following additional provisions will apply:

(a)   Prior to acquiring the Patient Care Decision Support Tool, the QI Committee will use reasonable efforts to assess the tool for potential bias or discrimination based on race, color, national origin, sex, age, or disability, including gathering and reviewing information from publicly available sources and requesting information from the developer.

(b)   Any potential bias or discrimination identified will be reviewed by the QI Committee for an assessment of whether there are any reasonable ways the potential for bias or discrimination might be mitigated by the Facility in its use of the Patient Care Decision Support Tool, including any guidelines or recommendations from the developer. If a potential for bias or discrimination based on race, color, national origin, sex, age, or disability is identified the end users of the Tool will be trained on the potential bias as well as any guidance or best practices for the use of the Tool in light of the potential for bias or discrimination.

4.   **Implementation of Generative AI Technology**. If Generative AI Technology is approved for use, the Facility will identify the appropriate Department leader or his/her designee who will work with the CTO or his/her designee to lead the implementation of the technology which will include:

(i)   *Identified Protocols*. The Facility will implement the protocols identified for use by the QI Committee, Finance Committee, or Executive Committee pursuant to Section 2 above. If, in the implementation, any protocol identified is determined by the Facility to be infeasible or insufficient, the applicable Committee will be notified, and they will work with the appropriate Department leader, Compliance Officer, and CTO or their designees to determine the best implementation strategy. If concerns arise in the implementation of Generative AI Technology, the Department leader and CTO should work with the Committee which approved the Generative AI Technology to address the concern.

(b)   *Acceptable Use Policy*. All Generative AI Technology must be implemented and comply with the Facility's Acceptable Use Policy. The CTO or his/her designee will be

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responsible for ensuring Generative AI Technology is implemented in accordance with the Acceptable Use Policy and monitoring the use thereafter to ensure continued compliance with the Acceptable Use Policy.

(c)   *Contract Review Policy*. Any agreement for the purchase or use of the Generative AI Technology will be reviewed in accordance with the Facility's Contract Review Policy, as supplemented by the "Supplemental Checklist for Generative AI Technology Contracts", a copy of which is attached to this Policy as Exhibit A.

(d)   *Informed Consent and/or Notice*.

(i)   Prior to utilizing any Generative AI Technology in the care of patients, the Facility will determine if the patient's consent is required and if so, will modify existing consent form(s) to include reference to the Generative AI Technology or create a new consent form to address the technology. If Generative AI Technology is used in connection with any research activity, the Facility will comply with its Research Activities Policy.

(ii)   If informed consent is not required the Facility will evaluate whether notice to patients is required or prudent. If the Facility determines patient notice is required or if it is not required but the Facility determines patient notice is prudent, the applicable Department leader and the Compliance Officer will work collaboratively to develop an appropriate notification process, which may include written notice, verbal notice documented in the patient's medical record, or general posts and signage within the Facility or on the Facility's website.

(iii)   If the Generative AI Technology utilizes any recording or surveillance technology, consent or notice will be implemented in accordance with the Facility's Recording & Surveillance Policy.

(e)   *Medical Record Documentation*. To the extent Generative AI Technology will be utilized in the generation of documentation included in the patient's medical record, providers and other users of the Generative AI Technology policy must comply with all Facility policies, applicable to the timely and accurate completion of medical records, including _____. In no event may a provider or clinician utilize Generative AI Technology in the generation of patient medical record documentation without reviewing the record for accuracy and completeness and ultimately signing the record within the time period required.

The Facility will update its policies relating to medical record documentation as needed to incorporate the use of Generative AI Technology.

(f)   *Use & Disclosure of PHI*. If a patient's individual identifying information will be utilized or accessed by the Generative AI Technology, additional protocols must be implemented to protect the confidentiality and security of patients' protected health information, including:

(i)   Notification of the Facility's Privacy & Security Officers upon approval of the Generative AI Technology;

(ii)   Facility's Security Officer will include the Generative AI Technology in its HIPAA Security Risk Assessment;

(iii)   Facility's Privacy Officer will maintain a copy of the signed Business Associate Agreement between the Generative AI Technology vendor and the Facility;

(iv)   The Privacy and Security Officers will determine what, if any, additional training may need to be provided to users of the technology and work with the appropriate Department leader(s) and CTO to provide and document the additional training.

(g)   *Billing, Coding, Revenue Cycle Policies*. To the extent Generative AI Technology is utilized in the billing, coding, or revenue cycle management process, the Department leader and/or his or her designee and the Facility's Chief Financial Officer will ensure the relevant policies applicable to the use of the Generative AI Technology in the billing, coding and revenue cycle management process are reviewed and updated if needed.

(h)   *Compliance*. Upon approval of any Generative AI Technology for use, the Compliance Officer will be notified and provided with all information relating to the Generative AI Technology the Compliance Officer deems necessary to address the use of the Generative AI Technology in the Facility's Compliance Program. Upon receiving notice of approval of Generative AI Technology, the Compliance Officer will include the Generative AI Technology in the Facility's compliance risk assessment and work with the Compliance Committee to identify risk mitigation measures to address the risks identified with the Generative AI Technology and include those strategies in the Committee's work plan.

The Department leader and CTO will work collaboratively with the Compliance Officer and the Compliance Committee to respond to compliance-related inquiries and address compliance-related issues in the implementation of Generative AI Technology or any risk mitigation strategies identified by the Compliance Committee and included in the Committee's work plan.

(i)   *Training*. The applicable Department leader(s) will be responsible for ensuring any users of the Generative AI Technology are appropriately trained on the Generative AI Technology, including the protocols for its use established by the Facility, the limitations of the technology, and any specific risks, addressing any privacy and/or compliance training recommended by the Privacy Officer and/or Compliance Officer, and how to report concerns relating to Generative AI Technology.

To the extent any Patient Care Decision Support Tool is identified as having the potential for bias or discrimination based on race, color, national origin, sex, age, or disability, the end users of the Tool will be trained on the potential for discrimination, including any best practices or guidance for its use, ways to mitigate the discrimination, and how staff should report potential discrimination or concerns.

5.   **Review & Assessment**. After the implementation of Generative AI Technology, the applicable Department leader and the CTO will periodically review and assess the performance of the Generative AI Technology which shall be no less frequently than annually;

provided, however, any Generative AI Technology used in patient care settings, in the billing and coding of services, or in the employment context must be reviewed at least quarterly for the first 24 months of the use of the Generative AI Technology. Thereafter, the QI Committee, Finance Committee, or Executive Committee, as applicable, may approve less frequent reviews provided a review occurs at least annually.

The ongoing evaluation and monitoring of any Patient Care Decision Support Tool will include a review of the potential for bias or discrimination if the Tool utilizes input variables that measure race, color, national origin, sex, age, or disability.

The review and assessment of the Generative AI Technology will be documented and reported, if applicable, to the QI Committee, Finance Committee, or Executive Committee which approves the use of the Generative AI Technology. Any concerns identified in the review and assessment will be appropriately reviewed by the applicable Committee, CTO, applicable Department leader(s), and the Compliance Officer and appropriate measures or action plan identified to address the concerns.

6. **Outside Use by Employees.**

Facility recognizes certain Generative AI Technologies provided by third parties are widely available to the public for use. Employees should only use Generative AI Technologies in the performance of their job duties if the Generative AI Technology is supplied or approved for use by the Facility in accordance with this Policy. An employee who wishes to utilize other Generative AI Technology to perform a job task must (i) first inform and get permission from his/her supervisor; (ii) must comply with this and all other applicable Facility policies in the use of the Generative AI Technology; and (iii) must not provide the Generative AI Technology any protected health information or other personal information of any individual, including Facility's employees, patients and donors; or any proprietary, confidential, or otherwise sensitive information of Facility.

7. **Complaints Regarding Bias or Discrimination**. Patients, providers, employees, and others may report complaints regarding potential bias or discrimination in the use of any Generative AI Technology by Facility, including Patient Care Decision Support Tools.

(a) *Employment-related complaints*. Any complaints regarding bias or discrimination relating to employees will be forwarded to the Vice President of Human Resources who will handle it in a manner similar to other employment-related discrimination claims.

(b) *Non-employment related complaints*. All other complaints will be forwarded to the Compliance Officer who will determine if the complaint is legitimate and has merit and if so, will proceed with an investigation. The investigation may be conducted by the Compliance Officer, his/her designee, or outside counsel. The investigative report and findings will be provided to the QI Committee if the investigation relates to a Patient Care Decision Support Tool or other Generative AI Technology initially evaluated by the QI Committee. For all other Generative AI Technology, the investigative findings and report will be provided to the Executive Committee. The applicable Committee will work with the Facility's legal counsel to determine how to address, mitigate and/or remedy any bias and/or discrimination confirmed by the investigation.

8.   **Regular Reporting**. As AI technology and the Federal and state regulations governing its use continue to evolve, the Facility desires its leaders, committees and the Board to stay abreast of current developments. The CTO and Compliance Officer are the individuals designated by the Facility as responsible for monitoring and regularly reporting to leaders, committees, and the Board on developments relating to AI technology and its regulation.

The groups receiving reports and the cadence of reporting will vary but "AI Developments" will be a standing agenda item on the following Committee meetings during which the CTO and Compliance Officer will provide the Committee with an update on the status of AI technologies and the regulations governing the use of AI technologies; implementation of Generative AI Technology within the Facility; and Facility policies and protocols relating to the use of Generative AI Technology:

[Insert Committees which will have AI Developments as a standing agenda item]

On at least an annual basis the CTO and Compliance Officer will provide the Board with an update on AI Developments.

Supplemental Checklist for Generative AI Technology Contracts

If Generative AI Technology (as defined by the Facility's Generative AI Policy referred to herein as the "Policy")) is identified as part of any purchase or services agreement the Facility is considering, the contract review will include the following:

1.   Identify the Intended Use(s) of the Generative AI Technology within the Facility.

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2.   Does the contract give the Facility the right to utilize the Generative AI Technology for the above intended use(s)? If not, ensure the contract is updated to include the intended use(s).

If the contractor will not agree to the updated intended use(s), the CTO and the applicable Department leader should re-evaluate the purchase and how the Generative AI Technology will be utilized which may include re-evaluation by the appropriate Committee in accordance with the Policy.

3.   Does the Generative AI Technology require FDA approval or clearance as a medical device and if so, does the contract contain a representation from the contractor that the Generative AI Technology has the requisite FDA approval? If not, does the contract include a representation that the Generative AI Technology is not AI-based software regulated as a medical device by the FDA?

4.   Does the contract include provisions requiring the contractor/developer to (a) comply with any transparency requirements relating to the Generative AI Technology, including requirements for predictive decision support interventions; or (b) provide Facility reasonably requires to ensure the safe, effective and compliant use of the Generative AI Technology, including information on how the developer avoids or limits the potential for bias.

If not request the contract be updated to include an obligation on the contractor/developer to provide this information upon the Facility's reasonable request which may be subject to the Facility agreeing to keep such information confidential if the information is not required by law or regulation to be provided to end users.

5.   If the contract does not contain a without cause termination right, include in the contract the right to terminate the contract without penalty in the event a change in law or regulation applicable to Facility makes continued use of the Generative AI Technology by Facility impractical or infeasible.

6.   Does the contract address copyright and other IP issues relating to the Generative AI Technology and its work product, including:

- ☐ Does the contractor represent it owns or has the necessary IP rights to give the Facility the right to use the technology in accordance with the contract's terms?
- ☐ Will the contractor indemnify and hold the Facility harmless for any claims it does not have these intellectual property rights?

□ Does the contract address potential copyright infringement from any work product generated by Generative AI Technology?

□ Has the Facility's IP counsel reviewed the contract and have any issues identified by counsel been resolved?

7. Will the contractor have access to or use protected health information ("PHI")? If so:

□ Confirm the parties will execute a Business Associate Agreement complying with HIPAA;

□ Facility must determine whether it will:
   o Limit the use of its PHI by the contractor/developer for the advancement of the Generative AI Technology to advancing the Generative AI Technology for the Facility only and prohibit the contractor/vendor from aggregating the Facility's PHI with other customers/users' PHI and using it to refine/advance services provided to other customers/users; or
   o Allow its PHI to be aggregated by the contractor/developer and utilized to improve Generative AI Technology as it applies to all users of the technology, including customers and users not affiliated with the Facility.

□ Depending on the Facility's decision above, ensure the contract and Business Associate Agreement include the required provisions to either limit the use or allow the use as allowed by HIPAA.

□ Ensure the contract/Business Associate Agreement prohibits any use of the Facility's PHI post-termination unless the PHI is de-identified in accordance with HIPAA or for the contractor's management/administration as allowed by HIPAA.

□ Has the Facility's HIPAA counsel reviewed the contract/Business Associate Agreement and have any issues identified by counsel been resolved?

8. Will the contractor have access to other confidential, proprietary, or sensitive information of Facility or of third parties maintained by Facility ("Confidential Information")? If so:

□ The contract must contain a confidentiality clause requiring the contractor to keep the Confidential Information strictly confidential and limiting its use/disclosure of Confidential Information.

□ Facility must determine whether it will:
   o Limit the use of its Confidential Information by the contractor/developer for the advancement of the Generative AI Technology to advancing the Generative AI Technology for the Facility only and prohibit the contractor/vendor from aggregating the Facility's Confidential Information with other customers/users' information and using it to refine/advance services provided to other customers/users; or
   o Allow its Confidential Information to be aggregated by the contractor/developer and utilized to improve Generative AI Technology as it applies to all users of the technology, including customers and users not affiliated with the Facility.

□ Depending on the Facility's decision above, the contract must contain provisions limiting or allowing the contractor/developer's use of the Confidential Information to reflect the Facility's position.

□ Provide for the return or destruction of the Facility's Confidential Information post-termination or if contractor/developer will be allowed to retain Confidential

Information post-termination does the contract limit the contractor/developer's use/disclosure of Confidential Information consistent with the Facility's position above and require any retained Confidential Information to continue to be maintained in a way that ensures its confidentiality.

☐ Require the contractor to comply with all federal and state laws applicable to the privacy, security, and confidentiality of any Confidential Information provided by the Facility to the contractor, including any state laws applicable to an individual's personal information.

☐ Has the Facility's legal counsel reviewed the confidentiality terms and have any issues identified by the Facility's counsel been resolved

9.   Does the contract contain a specific representation and warranty of contractor/developer that Generative AI Technology will at all times, as contemplated for use by Facility and its authorized users, comply with all Federal and state laws regulating the technology and will be updated as needed to ensure continued compliance with all Federal and state laws regulating the technology and its intended uses.