# Document Metadata

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priority\_phase: Must

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status: draft

## **Purpose**

To define the formal governance structure for AI and GenAI oversight across the hospital enterprise, integrating compliance, clinical, IT, and ethical controls.

## **Scope**

Applies to all AI systems managed, developed, or procured across the organization, including those used in diagnostics, ambient documentation, scheduling, patient interaction, and operational optimization.

## **Policy Statement**

The hospital must maintain an enterprise AI governance framework that enforces clear roles, lifecycle management checkpoints, ethics review, and internal accountability structures. Governance must incorporate sector-specific laws and emerging risks from GenAI technologies.

## **Roles and Responsibilities**

• Governance Committee: Reviews AI/GenAI systems at pre-deployment and annual checkpoints.

• Legal & Compliance: Maintains regulatory audit readiness and enforcement procedures.

• Model Risk Review Panel: Applies risk rating criteria across model types and vendors.

## **Implementation Phases**

### **Must Do**

• Require all GenAI models to pass governance review before deployment (GOV-4.2).

• Create and enforce AI system registration and version logging.

• Document governance decisions and system risk profiles in a central repository.

### **Should Do**

• Link AI governance checkpoints to hospital incident response and change control (SP 800-61r3).

• Use structured governance artifacts: risk rating matrix, model audit trail, usage logs.

### **Recommended**

• Implement ethical oversight workflows for models impacting patient consent, diagnosis, or treatment (AI 600-1 §2.5).

• Use governance analytics (e.g., drift detection dashboards, failure mode logs) to guide model reviews.

## **References**

• NIST AI RMF: GOVERN-4, GOVERN-5

• NIST AI 600-1: §2.1, §2.5

• FDA AI/ML SaMD: PCCP Guidelines (2024)

• HIPAA §164.308(a)(1)(ii)(D) – Evaluation

## **Review Cycle**

Every 12 months, or following a major incident, drift event, or regulatory change.