Applicability: UW Medicine[1] and UW Medicine Affiliated Covered Entity[2]

Policy Title: Use of Artificial Intelligence (AI)[3] in the Healthcare Setting

Policy Number: COMP.308

Superseded Policies: N/A

Date Established: July 18, 2025

Date Effective: September 2, 2025

Next Review Date: September 2, 2028

PURPOSE

The adoption of Artificial Intelligence (AI), including Generative AI (GenAI), presents an opportunity to accelerate UW Medicine's strategic, financial and operational goals. The use of this emerging technology has the potential to improve the quality and efficiency of healthcare and research that is integrated with the clinical environment. However, the use of AI poses unique characteristics associated with possible elevated risk. Such risks include but are not limited to: the privacy and security of data; Accuracy and integrity of Algorithm & Model; potential Bias; and potential impacts on the delivery of medical care and the patient experience. The purpose of this policy is to describe the following: 1) general requirements regarding the use of AI; 2) when a proposed use of AI requires internal review for assessment and mitigation of potential risks; and 3) when a proposed use of AI may be undertaken without any review.

This policy **does not** apply to Fred Hutchinson Cancer Center.

---

[1] UW Medicine is an integrated clinical, research and learning system with a single mission to improve the health of the public. The clinically integrated parts of UW Medicine consist of the following:
- Airlift Northwest
- Fred Hutchinson Cancer Center (Please note, the UW Medicine Compliance Program and this policy apply to UW faculty. Fred Hutch employees who are not also UW faculty are required to comply with Fred Hutch compliance policies only.)
- Harborview Medical Center
- UW Medical Center
- UW Medicine Primary Care
- UW Physicians
- UW School of Medicine

[2] The University of Washington (UW) is a hybrid covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), comprised of healthcare and non-healthcare components. For the purposes of HIPAA, the UW has designated healthcare components and further designates a group of healthcare components to be one affiliated covered entity known as UW Medicine Affiliated Covered Entity (UW Medicine ACE). Healthcare components of the UW Medicine ACE are represented in 101.G1 University of Washington (UW) HIPAA Designation – *UW Medicine – Affiliated Covered Entity.*

[3]Artificial Intelligence (AI), as referenced within this policy, can refer to an AI System or AI within a tool, application or use case.

This policy **does not** apply to education and research that does not meet the criteria as defined in Section C.

This policy is expected to evolve over time in response to rapid changes in this innovative technology, the legal and regulatory landscape and future inclusion of education and research not currently covered within this policy.

DEFINITIONS –See Guidance: [COMP.308.G1 UW Medicine AI Policy Glossary](#)

POLICY

A. General Requirements
1. This policy does not replace existing UW Medicine processes to approve Clinical Care, UW Medicine Business Operations, or research.
2. The use of any AI must comply with all relevant UW Medicine policies, including UW Medicine Compliance Patient Information Privacy policies and UW Medicine IT Services Information Security Standards.
3. The proposed AI use at UW Medicine must follow the established process for Internal Review if it meets the criteria set forth in Section B.
4. This policy:
   a. **Applies** to all actual or proposed AI uses for clinical care or UW Medicine Business Operations.
   b. **Applies** to research within the scope of Section C.
   c. **Does not** apply to education or to research outside the scope of Section C.

B. AI Uses for Clinical Care and UW Medicine Business Operations Requiring Internal Review. When a proposed AI use for Clinical Care or UW Medicine Business Operations entails any of the characteristics described in Section B.1. and is not within the appropriate use scope and parameters outlined on the UW Medicine Approved AI Tool/Application List (see [Vitals](#) for list), then it is considered to have possible elevated risk and the proposal must undergo Internal Review as described in Section B.2.

1. AI Characteristics Associated with Possible Elevated Risk:
   a. Its output is patient-facing.
   b. It directly affects documentation in the electronic health record (EHR).
   c. It is trained on, has access to or individuals could input identifiable clinical data (including PHI), including Limited Data Sets.
   d. It is trained on, has access to or individuals could input UW Medicine De-Identified Health Information that could be accessed by a third party (e.g., vendor or otherwise) or could leave the Secure UW Medicine Environment and has not been certified as de-identified through the Honest Broker process.
   e. It is trained on, has access to or individuals could input UW Medicine Data (e.g., sensitive data such as legal, financial, IP, PII, confidential/proprietary, trade secret, subject to contractual sharing limitations).
   f. It affects and/or automates Clinical Care (e.g., diagnostics or decision-making) with or without human validation of output.
   g. It affects and/or automates clinical coding/billing with or without human validation of output, and/or is designed to impact clinical coding/billing.

h.   It augments or fundamentally changes the work functions of represented (unionized) staff or trainees.

i.   It requires significant financial investment, exceeding $100,000 (either one-time cost or annually, including internal labor).

j.   It involves a new/unique vendor to UW Medicine (e.g., no existing contractual arrangement with the vendor).

k.   The error rate of the system, as assessed by UW or neutral third-party, is higher than current standard practice (or error rate is unknown).

l.   It presents equity or accessibility impacts (e.g., as determined when reviewing against the Equity Impact Review Tool).

m.   It involves 2,000 or more users.

2.   <u>Internal Review</u>. Proposed AI use, which has characteristics associated with possible elevated risk described in Section B.1., will be subject to an initial review by leveraging the UW Medicine IT intake process for Clinical Care and UW Medicine Business Operations, as described further in Procedures below. If appropriate, a secondary review may be required.

a.   <u>Initial Review</u>. An initial review will be conducted to ensure that relevant risks are identified and approval may be granted if appropriate controls are implemented to mitigate the risks.

b.   <u>Secondary Review</u>. Secondary review may be triggered by certain characteristics associated with possible elevated risk and/or if appropriate controls cannot be implemented to mitigate risks during the initial review.

C.   <u>AI Uses Requiring Internal Review for Research</u>. When research is conducted by a UW School of Medicine principal investigator (PI) that involves the use of AI, either UW Medicine Data or targeted enrollment of UW Medicine patients, and that requires UW Institutional Review Board (IRB) review, the UW IRB will conduct the Internal Review as part of the IRB review. The components of this augmented review include: expanding how UW Human Subjects Division (HSD) defines human research to include the use of data that is at high risk of re-identification; developing guidance for research involving AI, and; requiring a UW Medicine security review. These added components will help UW IRB to ensure that relevant AI risks are identified and if appropriate controls are implemented to mitigate the risks.

D.   <u>AI Uses Not Requiring Internal Review</u>. Notwithstanding the above, proposed AI uses that are not research requiring UW IRB review and that do not contain any of the characteristics associated with possible elevated risk described in Section B.1. are considered 'low risk' and are permitted without the need for Internal Review. These AI uses must adhere to other existing processes. Examples of 'low risk' AI uses include:

1.   Any tool listed on the UW Medicine Approved AI Tool/Applications List (see [Vitals](#) for list) and used within the appropriate scope and parameters.

2.   Using ChatGPT to synthesize a published scholarly paper concisely for personal review.

3.   Using an auto-completion tool built into Microsoft Office 365.

4.   Using DALL-E to create an image for a Microsoft PowerPoint presentation.

5. Using ChatGPT to develop content, so long as neither the prompt nor any other content provided to or accessible by ChatGPT is UW Medicine Data and the generated content is carefully vetted for Accuracy.

6. Using web-based Microsoft CoPilot to create a schedule or agenda for a meeting.

PROCEDURES

A. Internal Review. Any proposed AI use requiring internal review will be initiated through one of two pathways: IT Intake or IRB Intake.
   1. IT Intake. For Clinical Care and UW Medicine Business Operations, the submission of a "New Project Request" on the UW Medicine IT Project Intake Page (AMC login required) is required. The IT process was augmented to enable the identification of AI use cases and support the AI review and assessment processes.

   2. IRB Intake. To determine if a research study involving AI requires Internal Review by the UW IRB, complete the Human Subjects Research Determination Worksheet.
      a. If the worksheet indicates UW IRB review is required, submit a UW IRB Application through Zipline.

B. Contract Requirements.
   1. For Clinical Care and UW Medicine Business Operations arrangements involving a third party/vendor, a written agreement can only be executed with appropriate UW or UW Medicine delegation of authority after the proposed AI use undergoes proper Internal Review and approval. For research, contracting review and approval processes may occur concurrently with Internal Review.
   2. The written agreement must be reviewed by the Attorney General's Office, Risk Management and/or the appropriate contracting team (e.g., UW Procurement, UW Medicine Supply Chain, UW School of Medicine Regulatory and Business Affairs, UW Office of Sponsored Programs, etc.) to identify risks and ensure contractual safeguards are in place before using the proposed AI product in a healthcare setting.
   3. If appropriate, the agreement may include an IT rider. Any (proposed) changes to the IT rider must be reviewed and approved by UW Medicine IT Services.
   4. A Business Associate Agreement (BAA) and/or Data Use Agreement (DUA) must be executed if the arrangement involves UW Medicine PHI, and the data recipient meets the definition of a business associate. UW Medicine Compliance must review the BAA before using the proposed AI product with UW Medicine PHI.

C. Privacy and Security Assessments.
   As part of the IT Intake or IRB Intake processes referenced in Procedures Sec. 1A and Sec. 1B, UW Medicine Compliance and the UW Medicine Information Security Program must review any AI use in which this policy applies to assess the level of privacy and information security risk it poses to the organization. As appropriate, the UW Medicine Information Security Program will conduct an initial and periodic assessment of the security controls in place.

PROCEDURE ADDENDUM(s) REFERENCES/LINKS
- COMP.308.G1 UW Medicine AI Policy Glossary
- COMP.103 Use and Disclosure of Protected Health Information
- COMP.106 Use and Disclosure of Protected Health Information by Business Associates
- SS-06 Information Security Risk Management Standard
- SS-12 Acceptable Use Standard

APPROVALS

/s/ Beth DeLair   8/27/2025
Beth DeLair   Date
Chief Compliance Officer, UW Medicine
Associate Vice President for Medical Affairs, UW