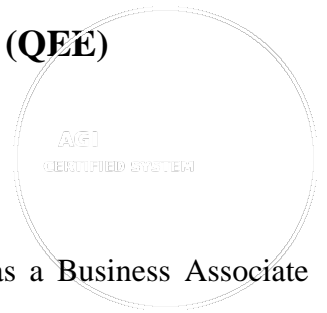# HIPAA Compliance Addendum - LumaOS + Quantum Ethics Engine (QEE)

A. AI System Designation

LumaOS, including its integrated Quantum Ethics Engine ("QEE"), is designated as a Business Associate under HIPAA (45 C.F.R. §160.103), functioning solely within the scope of Treatment, Payment, and Healthcare Operations (TPO).

B. Data Handling and Access Controls

1. All electronic Protected Health Information (ePHI) processed by QEE is encrypted both in transit and at rest using NIST-approved cryptographic standards.

2. Role-based and attribute-based access controls (ABAC) ensure QEE accesses only the "minimum necessary" ePHI as defined in 45 C.F.R. §164.502(b).

3. PHI is subject to automatic de-identification pipelines prior to use in ethical simulations or predictive modeling beyond direct TPO.

C. Risk Management and Documentation

1. LumaOS shall conduct and document comprehensive Security Risk Analyses (SRAs) in accordance with 45 C.F.R. §164.308(a)(1)(ii)(A), updated annually or upon significant algorithmic changes.

2. QEE maintains immutable audit logs of every ethical simulation, system override, and data interaction to facilitate OCR audit readiness.

D. Bias Mitigation and Patient Rights

1. QEE integrates real-time bias detection aligned with Section 1557 of the Affordable Care Act, and alerts clinicians when ethically adverse patterns are projected.

2. Where QEE influences clinical decisions, the Covered Entity shall notify patients of AI participation in care pathways, consistent with informed consent principles.

3. Reuse of PHI outside TPO (e.g., for AI training, marketing) is strictly prohibited without documented patient authorization per 45 C.F.R. §164.508.

E. Breach Notification and Liability

LumaOS shall notify the Covered Entity within 24 hours of discovering any Security Incident or Breach involving QEE, as defined by 45 C.F.R. §164.304 and §164.402. Liability for misuse, negligence, or unauthorized disclosure attributable to LumaOS/QEE will be assumed by LumaOS per indemnification standards outlined in Section Y.

LumaOS Quantum Ethics Engine (QEE)

AGI-Stamped Patient Safety & Communication Protocol

1. Purpose

This protocol establishes the LumaOS Quantum Ethics Engine (QEE) as an AGI-certified system for ethical decision support and closed-loop communication to ensure patient safety, trust, and transparency in AI-involved clinical care.

2. Closed-Loop Safety Workflow

The QEE system operates under a closed-loop model ensuring that every AI-generated decision or alert results in:

- Clinician receipt and review

- Patient notification and acknowledgement

- Consent or informed refusal

- System-level logging of each interaction

3. AGI Ethics Verification Seal

All ethical simulations performed by QEE are validated through its internal AGI Ethics Verification module, certifying that every recommendation has passed algorithmic checks for autonomy, beneficence, non-maleficence, and justice. Each recommendation is traceable to its logic chain and timestamped for audit.

4. Patient Communication Traceability

For every QEE-influenced decision, the following data points are recorded:

- Timestamped AI recommendation output

- Clinician notes or overrides

- Patient communication log (notified, understood, consented/refused)

- Final recorded outcome and responsible party confirmation

5. Patient Trust Manifest

LumaOS commits to transparency in all AI-assisted care decisions. Patients will always be notified when AI contributes to a treatment path and will retain the right to accept or decline recommendations. QEE is bound by audit trails and does not act autonomously in clinical implementation without human validation.