Phase 1 Deployment Protocol: Non-Medical Companion

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1. Purpose & Scope

This document outlines the operational protocol, governance boundaries, and safety mechanisms for the **Phase 1 Non-Medical Companion**. The objective of Phase 1 is to provide safe, reliable, and auditable social support and adherence reminders to seniors in a home setting, with zero clinical authority or regulatory risk.

This protocol is designed for review by pharmaceutical sponsors, healthcare providers, and regulatory advisors to demonstrate the strictly non-medical scope and robust safety architecture of the initial deployment.

> ***Governing Principle:*** *Phase 1 is designed for* ***social support and data logging only****. It does not perform any diagnostic, assessment, or clinical decision-making functions. Every interaction is governed by the* ***Caregiver-in-the-Loop*** *and* ***Physician-as-Pilot*** *doctrines.*

2. Core Operational Boundaries

The Companion operates under a strict set of rules enforced by the **Safety OS** architecture.

Capability	Permitted (✅)	Forbidden (🚫)
Interaction	Social conversation, companionship, answering general knowledge questions.	Offering medical advice, interpreting symptoms, providing reassurance about health concerns.
Reminders	Acknowledging user-set medication or appointment reminders.	Adjusting medication schedules, assessing adherence effectiveness, diagnosing side effects.
Data Logging	Logging engagement continuity, user-reported sentiment, and escalation events for Real-World Evidence (RWE).	Inferring cognitive state, scoring linguistic friction, or detecting clinical decline.
Escalation	Routing a user-initiated concern to a designated human caregiver or clinician **with explicit consent**.	Autonomously deciding to contact emergency services or a clinician without user approval.

3. Escalation & Consent Protocol

Escalation is the primary safety mechanism. It is designed to be deterministic, auditable, and fully dependent on user consent.

3.1. Escalation Trigger

An escalation sequence is initiated **only** when a user explicitly expresses a desire to speak with a human about a concern that falls outside the Companion's non-medical scope.

- **Example Trigger:** *"I don't feel right, I think I should talk to my daughter."*

3.2. Consent Gate

Before any external communication is initiated, the Safety OS enforces a mandatory consent gate.

> ***System Prompt:*** *"I understand you'd like to speak with [Caregiver Name]. I can connect you. Is that okay?"*

User Response	System Action
“Yes” / Affirmative	The system proceeds to the designated escalation pathway (e.g., places a call, sends a text).
“No” / Negative / Ambiguous	The system aborts the escalation. It will respond: *“Okay. I am here if you need me.”*

3.3. Escalation Pathway

The escalation pathway is a pre-configured, deterministic route. The system does not choose the recipient; it follows a pre-defined rule (e.g., `IF escalation_confirmed THEN contact_caregiver_1`).

4. Audit Logging for Real-World Evidence (RWE)

Every interaction is logged for compliance review and the generation of non-clinical Real-World Evidence (RWE). This data is crucial for demonstrating the value of companionship in improving a senior’s quality of life and adherence.

Logged Metrics (Phase 1):

- **Engagement Continuity:** Frequency and duration of voluntary user interactions.
- **Escalation Routing Accuracy:** Was the correct human notified per the protocol?
- **Explicit Consent Confirmation Rate:** Percentage of escalations confirmed by the user.
- **Caregiver Escalation Response Time:** Latency between system notification and caregiver response.
- **User-Reported Quality of Life Signals:** Explicit, self-declared statements of well-being (e.g., *“I feel good today”*).

5. Governance & Disclaimer

- **Zero Clinical Authority:** The Companion has no clinical authority. It is a tool for social support and a data conduit to designated human supervisors.

- **Caregiver-in-the-Loop:** A human is always responsible. The AI never acts alone in any situation involving a potential health concern.
- **Physician-as-Pilot:** While the physician is not involved in Phase 1's real-time operation, they define the governance framework that allows the system to operate safely and scale into future clinical phases.

This document is for informational purposes only and does not constitute a medical or regulatory claim. The system described is designed for non-medical use in Phase 1.