

Protocol Governance & Escalation Framework

This protocol operates under predefined structural constraints designed to prevent premature escalation and bias-driven decision-making.

This section exists to protect:

- Biological stability
- Data integrity
- Longitudinal clarity
- Future applicability
- Emotional neutrality

Core Principle:

Certainty is not available.

Stability is.

Escalation does not eliminate uncertainty about the future.

Structure does.

Dose Rules:

- Baseline: 1 g daily
- Formal review permitted at 9 months
- Escalation strongly discouraged before 12 months
- Escalation steps limited to: 1 g → 1.5 g → 2 g
- Absolute ceiling: 2 g
- Minimum 12 months at each dose before further increase
- 30-day written waiting period before any escalation

Escalation Criteria:

Escalation is justified only if:

- $\geq 10-15\%$ measurable improvement beyond baseline variability
- Sustained ≥ 3 months
- Confirmed by repeatable functional measures
- Not explained by confounders

Biochemical marker movement alone does not justify escalation. (VLCFA Test)

Non-Justifications for Escalation:

Escalation is NOT justified by:

- Anxiety
- Fear of missing opportunity
- Temporary enthusiasm
- Isolated biomarker fluctuation
- Novelty response

Chronic Lipid Acknowledgment:

Nervonic acid is not correcting a deficiency.

It is modifying structural lipid pools.

Long-term physiological trade-offs are possible.

Absence of side effects does not equal biological neutrality.

Psychological Safeguard:

The primary risk in this project is not lack of knowledge.

It is the combination of analytical drive, emotional investment, and rare disease isolation.

This framework exists to prevent intensity from overriding discipline.

Escalation Confirmation Requirement:

Any dose increase requires written confirmation that criteria are met.

If escalation is easy, it will occur.

Friction protects the experiment.

This framework exists because rare disease creates emotional urgency.

Clear constraints protect long-term data integrity and safety.

Stability is the objective, not intensity.