WISL™ No.89

Research Study Mission Proposal for Clinical Validation

Toa Payoh RTS — A13b Zone-Local LiDAR Sensing Lane

Non-Agentic AI Governance Singapore · UEN 53522354D Parent Patent SG020603109STW · P-LIFE 1.00™ · NAI 2.0 Edition: Draft for site survey and stakeholder review, 2026

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1. Purpose

This proposal sets out a bounded validation pathway for a non-agentic eldercare fall-monitoring system, forming the clinical evidence component of an HSA Class B Software as a Medical Device submission.

It is a validation study, not a deployment. No clinical operation, treatment replacement, or autonomous decision-making is proposed at any stage.

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2. Study Stack

Four filed components, integrated as one bounded environment. None actuates.

Component	Function	IPOS Application
A8 Bridged Layer	Nursing-home bridge; sole ingress chokepoint	10202602225P
x.1 / A13b	Zone-local 905nm LiDAR sensing lane	—
WD117	Immutable forensic ledger	10202602223T

Non-B1 Shell	Clinical advisory monitoring; alerts only	10202602270V

Governed under the ABC+2S+H Guardian Framework™ (10202600902P).

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3. Boundary Conditions

Six conditions define the architecture and are verifiable by physical inspection:

1. Voxelisation occurs inside the sensing node.
2. No raw point-cloud data egresses any node.
3. Only Centre-of-Mass vectors cross the silicon wall into the A8 bridge.
4. WD117 is write-once, one way in; no return path to facility IT.
5. The Non-B1 shell holds no actuation or control rights.
6. Nurse alerting runs on a dedicated annunciator cable, independent of facility IT and nurse-call networks.

Condition 1 is what makes the 3ZEROS™ privacy claim verifiable per zone rather than asserted system-wide.

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4. Stage 1 — Site Survey (Non-Interventional)

No human participants. No patient data. No ethics approval required.

- Zone identification and measured coverage geometry
- Node count derived from survey, not pre-specified
- Boundary-condition verification against §3
- Alert cable routing assessment
- Workflow observation at the nurse station
- Installation readiness: SR-01–04, BR-01, LG-01, AL-01, CB-01, AN-01

Closes at a GO / CONDITIONAL-GO / NO-GO decision gate with signed record.

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5. Stage 2 — Clinical Validation (Subject to Approval)

Requires a separate protocol, a named clinician investigator, and ethics approval before commencement.

Sponsor: Non-Agentic AI Governance Singapore (legal manufacturer). Principal Investigator: to be appointed — a qualified clinician at the participating institution.

Single site (Toa Payoh Hearth). Multi-site is a declared future phase, not part of this proposal.

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6. Endpoints and Acceptance Criteria

A Clinical Evaluation Plan (CEP) stating endpoints and acceptance criteria in numeric form will be issued before any data collection. Criteria set after data are seen carry no evidential weight.

Primary

- **Fall-event detection sensitivity**
- **False alarms per bed-night**

Secondary

- **Specificity; missed-event rate**
- **Time-to-alert; time-to-clinician-acknowledgement**
- **Unacknowledged-alert rate (see §7)**
- **Node-loss detection-to-annunciation time (VT-09)**

The bathroom is the load-bearing zone: fall risk concentrates there and camera-based sensing is not an acceptable answer.

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7. Authority Drift as a Measured Variable

Deployed monitoring fails less often through sensor error than through erosion of human response, in three phases:

1. **Advisory — recommendations reviewed with engagement.**
2. **Surrender — alert fatigue produces rubber-stamping.**
3. **Passive Observer — the system becomes the de facto decision-maker.**

WD117 records not only system events but the presence or absence of meaningful clinician response. This makes phases 2 and 3 visible rather than inferred, and supplies hardware evidence against the deployer and user accountability strands of MOH/HSA AIHGIe 2.0.

To the authors' knowledge, no deployed fall-monitoring system currently reports this measure.

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8. Comparator and State of the Art

- **Baseline: HPB–MOH Clinical Practice Guidelines on Falls Prevention among Older Adults Living in the Community**
- **Comparator research: Duke-NUS Centre for Ageing Research & Education — SAFE-TECH and prior falls-prevention trials**
- **National cohort reference: TARGET (2,291 residents aged 60+, 2022–2024)**

The Clinical Evaluation Report appraises this study alongside the above, not in isolation.

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9. Standards Position

Standard	Application
ISO 14971	Risk management
IEC 62304	Software lifecycle (software safety class determined separately from device class)
IEC 62366-1	Usability engineering — alert burden and clinician workflow
IEC 60601-1-2	Electromagnetic compatibility
IEC 81001-5-1	Health software security lifecycle

Conformity with recognised standards is the compliance route for HSA registration. EU AI Act Article 14 human-oversight principles are adopted as an ethical reference above that floor, not as a substitute for it.

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10. Limitations

All performance figures in the NAIGE corpus are design-intent specifications pending validation. No hardware prototype has been submitted for regulatory assessment as

at the date of this proposal. Zone descriptions are indicative until the measured site survey is complete.

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11. Indicative Sequence

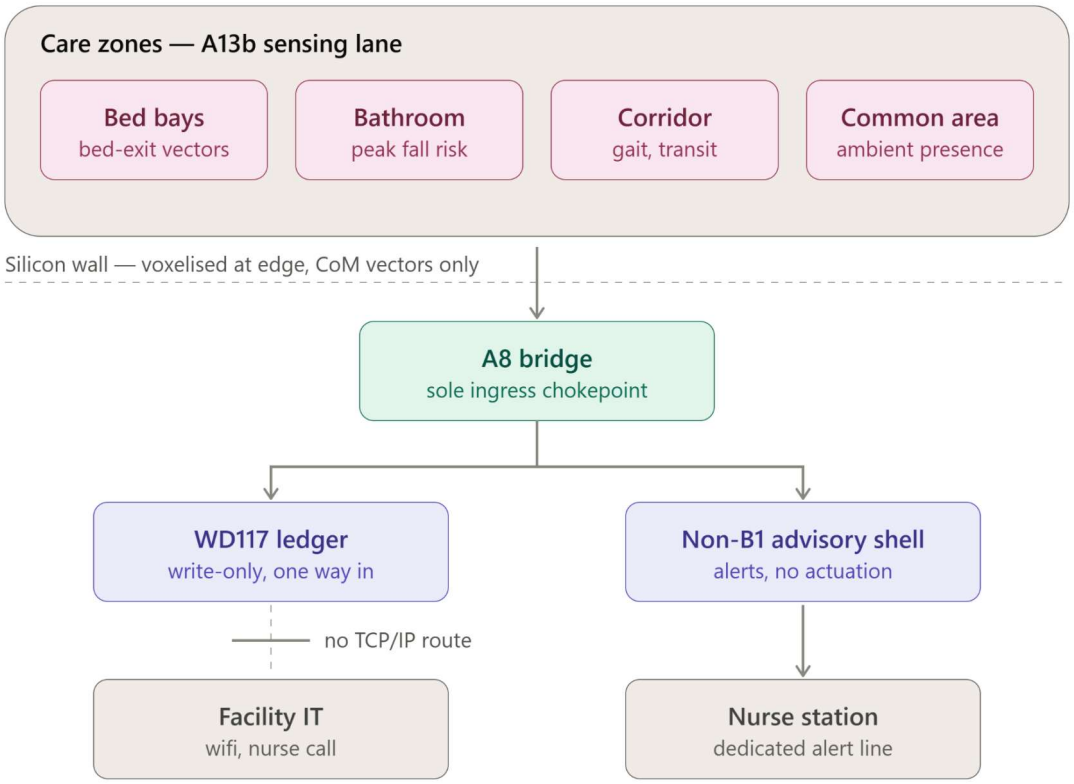
Period	Activity
Q3 2026	**Site survey; CEP drafted; investigator approached**
Q4 2026	**Decision gate; ethics submission prepared**
Q1 2027	**Stage 2 subject to approval**
2027	**Clinical Evaluation Report; HSA pre-submission**

The international patent decision runs as a separate track with its own deadline, determined by priority dates rather than by study progress.

AI-assisted drafting tools were used for prose and structuring only. Intellectual authorship, patent claims, and IP ownership remain solely with Edwin Koh Wui Kiat.

The Toa Payoh RTS study tests a zone-local A13b LiDAR sensing lane in which voxelisation occurs at the node, only CoM vectors cross the silicon wall into the A8 bridge, WD117 records write-only forensic state, and the Non-B1 shell drives a dedicated annunciator on an isolated cable.

The diagram supports the interpretation that **A13b voxelisation happens at the node edge before the A8 bridge**, with only CoM vectors crossing the silicon wall. The layout also makes the **WD117 ledger** and **Non-B1 advisory shell** separate downstream paths, which matches a fail-loud, no-raw-data-exfiltration stance.

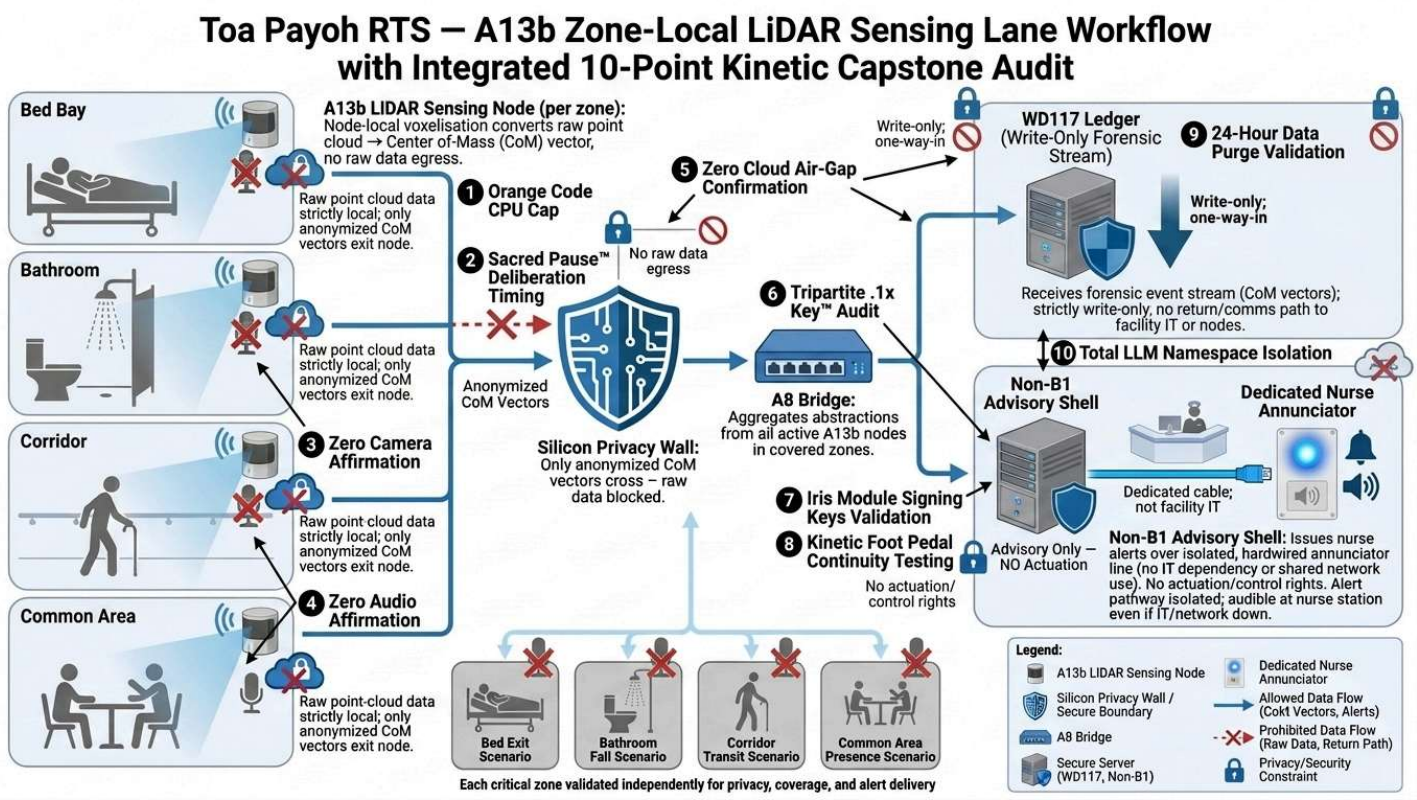


Zone handling

The current zone labels are fine as **indicative placeholders.** Once the Toa Payoh site survey is available, the ward layout should be swapped in directly, because node count, coverage geometry, and alert cable routing should all follow the real plan rather than a generic diagram

Three design points

- **Node-local voxelisation.** Each A13b unit should convert point cloud data into CoM vectors in-room, so raw spatial data never leaves the device boundary. That makes 3ZEROS something you can verify by physical inspection at each zone, rather than a system-wide claim
- **Bathroom as the critical zone.** The bathroom is the load-bearing validation area because fall risk is concentrated there and camera-based sensing is not an acceptable answer. If the study proves anything, it should prove performance there first
- **Dedicated alert path.** The hardest issue is the alert route, because the system must reach a nurse without breaking isolation. A dedicated annunciator cable driven by the Non-B1 shell preserves the architecture better than routing through facility IT or nurse-call networks



A13b Sensing Node Clinical Deployment and Functionality

Care Zone	Primary Activity Monitored	Sensing Technology	Voxelisation Process	Data Output Type	Jerk Resolution	Downstream Destination	Privacy Enforcement Mechanism
Bed bays	Bed-exit vectors	905nm LiDAR sensors	Node-local voxelisation (edge-processing; 96-cell voxel grid)	Anonymised Center-of-Mass (CoM) vectors	±0.05 mm	A8 bridge	Silicon privacy wall (Node-level data destruction; physical hardware barrier)
Bathrooms	Peak fall risks	905nm LiDAR sensors	Node-local voxelisation (edge-processing; 96-cell voxel grid)	Anonymised Center-of-Mass (CoM) vectors	±0.05 mm	A8 bridge	Silicon privacy wall (Node-level data destruction; physical hardware barrier)
Corridors	Gait and transit tracking	905nm LiDAR sensors	Node-local voxelisation (edge-processing; 96-cell voxel grid)	Anonymised Center-of-Mass (CoM) vectors	±0.05 mm	A8 bridge	Silicon privacy wall (Node-level data destruction; physical hardware barrier)
Common areas	Ambient presence	905nm LiDAR sensors	Node-local voxelisation (edge-processing; 96-cell voxel grid)	Anonymised Center-of-Mass (CoM) vectors	±0.05 mm	A8 bridge	Silicon privacy wall (Node-level data destruction; physical hardware barrier)

The A13b sensing node serves as the system's frontline hardware for data capture and edge-processing, deployed directly within specific clinical care zones to monitor patient activity safely.

Its primary roles and functionalities include:

- **Targeted Zone Monitoring:** The A13b nodes are deployed across distinct care settings to track specific activities. This includes monitoring bed bays for bed-exit vectors, bathrooms for peak fall risks, corridors for gait and transit tracking, and common areas for ambient presence.
- **Node-Local Voxelisation:** The most critical role of the A13b node is executing a secure edge-computing process known as **node-local voxelisation**. When the unit captures raw 3D point-cloud data via its LiDAR sensors, it processes this information entirely inside the unit itself—meaning the processing happens directly in the room. The node strips the raw spatial data down and converts it into anonymised Center-of-Mass (CoM) vectors.
- **Enforcing the Silicon Privacy Wall:** By performing this conversion internally, the A13b node physically enforces the system's "silicon privacy wall". It guarantees that raw, identifiable point-cloud data never crosses the device boundary or leaves the room. Only the completely sterile, anonymised CoM vectors are permitted to exit the node and travel downstream to the A8 bridge for system aggregation.
- **Verifiable Privacy:** Because this data destruction and vector generation happen physically at the node level, the system's strict privacy constraints can be verified by physical inspection at each individual A13b unit, rather than relying on vulnerable system-wide software claims.
- **Kinetic Enforcement:** Within the broader system architecture, the A13b specific module is designated for "Kinetic Enforcement," mapping these movements with an extremely high precision of ±0.05 mm jerk resolution.

In summary, the **A13b node** acts as a physical privacy barrier, safely translating raw environmental tracking into anonymized movement data before the broader monitoring system ever accesses it