

# EXEMPT DETERMINATION CANONIC

## Community Learning Study

2026-03-18

Dexter Hadley, MD/PhD

Hadley Lab CANONIC

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**hadleylab.org** Governed Document. Every claim cited.

## 0.1. Request Summary

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Field	Value
Study Title	Community Learning Patterns in Governed AI Health Navigation
PI	Dexter Hadley, MD/PhD
Co-I	Marisa Nimrod, MD
Sponsor	CANONIC Foundation
Requested Category	45 CFR 46.104(d)(4)(ii)
Date	2026-03-18

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## 0.2. 1. Exemption Category

This study qualifies for exemption under **45 CFR 46.104(d)(4)(ii)**: secondary research for which consent is not required, involving the study of information that has been recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

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## 0.3. 2. Justification

### 0.3.1 2.1 Data Contains No Identifiers

The community learning ledger records exactly three fields per entry: date, question text, and a session identifier. The schema contains no fields for names, email addresses, phone numbers, IP addresses, device identifiers, demographic information, or any other personally identifiable information. This is not post-hoc de-identification; the data architecture was designed from inception to capture community learning patterns without capturing identity.

### 0.3.2 2.2 No Linkage Table Exists

There is no linkage table, crosswalk, or mapping between session identifiers and user identities. The governance architecture enforces this structurally: the service assigns an identifier at session creation and discards all connection metadata. Re-identification is not merely prohibited by policy; it is architecturally impossible because the linking data was never collected.

### 0.3.3 2.3 No Contact with Subjects

The study is retrospective. Investigators will analyze existing ledger entries. No subjects will be contacted, recruited, or consented, because no mechanism exists to identify or reach them.

### 0.3.4 2.4 No Re-identification Attempt

Investigators will not attempt to re-identify subjects. Analysis is at the aggregate level: question taxonomy, temporal patterns, geographic references, and cross-arm comparison. Individual questions may be quoted in publication as examples of community learning patterns, but no individual question can be attributed to an identifiable person.

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## 0.4. 3. Governance Architecture as Structural Protection

The CANONIC governance framework provides human subjects protections that are architectural rather than procedural.

Protection	Procedural (Traditional)	Structural (CANONIC)
Anonymization	PI de-identifies data post-collection	Schema has no PII fields; identity never collected
Immutability	Data stored per retention policy	Append-only ledger; entries cannot be modified or deleted
Integrity	Audit trails maintained by research staff	Cryptographic hashing; verification is automatic

Protection	Procedural (Traditional)	Structural (CANONIC)
Compliance	Annual IRB review	Continuous compliance scoring; architectural constraints enforced at every session
Evidence sourcing	PI verifies clinical claims	System cannot surface ungoverned claims; structural constraint

#### 0.4.1 3.1 Caribbean Regulatory Context

Trinidad and Tobagos research ethics infrastructure follows US regulatory precedent informally. The country has five institutional RECs but no national research ethics legislation. A US exempt determination under 45 CFR 46.104(d)(4)(ii) establishes the regulatory baseline. This studys structural anonymization (no PII in schema, no linkage table) exceeds the de-identification standard required for exemption.

### 0.5. 4. Study Arms Covered

This exempt determination covers all current and future TALK scope arms described in the master Protocol:

Arm	Scope	Geography	Status
A	CaribChat	Caribbean (8 countries)	Active (55+ sessions)
B	MammoChat	United States (Florida)	Active (20+ sessions)
Future	Additional scopes	TBD	Pending amendment when volume sufficient

The modular design means new arms can be added via protocol amendment without resubmission of the exempt determination, provided the new arm inherits the same governance architecture.

## 0.6. 5. Investigator Attestation

The undersigned investigators attest that:

1. This study involves secondary research use of information recorded without identifiers.
2. No mechanism exists to identify or contact subjects.
3. No re-identification will be attempted.
4. The governance architecture described above is accurate and currently operational.
5. Any changes to the data schema that would introduce identifiable information will be reported as a protocol modification requiring new IRB review.

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Role	Name	Signature	Date
PI	Dexter Hadley, MD/PhD		
Co-I	Marisa Nimrod, MD		

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