WAIVER OF INFORMED CONSENT CANONIC Community Learning Study

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hadleylab.org Governed Document. Every claim cited.

0.1. 1. Regulatory Basis

This waiver is requested under 45 CFR 46.116(f)(3), which permits an IRB to approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or to waive the requirement to obtain informed consent, provided the IRB finds and documents all of the following:

0.2. 2. Required Findings

0.2.1 2.1 The research involves no more than minimal risk to the subjects

The study analyzes anonymized questions from a community learning ledger. The data schema contains no personally identifiable information: no names, no email addresses, no phone numbers, no IP addresses, no device identifiers, no demographic data. The data was designed from inception to be structurally anonymous. There is no intervention, no randomization, and no clinical data collection. The risk to subjects is no greater than that encountered in daily life.

0.2.2 2.2 The research could not practicably be carried out without the waiver

Users interact with public-facing AI health navigation services. The community learning ledger captures questions as they are asked, in real time, with structural anonymization at the point of capture. Requiring prospective informed consent for retrospective analysis of anonymized, non-identifiable questions would be impracticable for three reasons:

1. **No contact mechanism:** There is no way to identify or contact the individuals who asked the questions. No linkage table exists. No PII was ever collected.
2. **Fundamental alteration:** Requiring consent would fundamentally alter the community learning model, which operates on the principle that every question contributes to community intelligence automatically and anonymously.
3. **Retrospective design:** The study analyzes questions that have already been asked and ledgered. Prospective consent for retrospective analysis of non-identifiable data is logically incoherent.

0.2.3 2.3 The waiver will not adversely affect the rights and welfare of the subjects

The waiver does not affect subjects rights because the subjects cannot be identified. The data was anonymized by architectural design, not by post-hoc de-identification. There is no mechanism by which the waiver could adversely affect any identifiable individual because no individual is identifiable.

Furthermore:

- The community learning model is disclosed in the terms of service for all TALK instances.
- Users are informed that their anonymized questions contribute to community learning.
- No clinical data, diagnoses, or treatment information is collected or analyzed.
- Analysis is at the aggregate level; individual questions may be quoted as examples but cannot be attributed to identifiable persons.

0.2.4 2.4 Whenever appropriate, subjects will be provided with additional pertinent information after participation

Not applicable. Subjects cannot be identified or contacted. No additional information can be provided because there is no mechanism to reach any individual subject. This criterion is inherently satisfied when the data is structurally anonymous.

0.3. 3. Additional Justification

0.3.1 3.1 Structural Anonymization vs. De-identification

Traditional consent waivers for de-identified data rely on the assumption that identity was once known and then removed. This study is fundamentally different: identity was never collected. The distinction matters because:

Approach	Identity collected?	Linkage table?	Re-identification risk
De-identification (HIPAA Safe Harbor)	Yes, then removed	May exist	Non-zero (linkage attack)
De-identification (Expert Determination)	Yes, then assessed	May exist	Assessed as very small
Structural anonymization (CANONIC)	Never collected	Does not exist	Zero (no data to link)

The CANONIC governance framework enforces structural anonymization at the architectural level. The data schema has no PII fields. The system assigns a random session identifier at creation and discards all connection metadata. Re-identification is not merely prohibited; it is architecturally impossible.

0.3.2 3.2 Community Benefit

The community learning ledger exists to benefit the communities it serves. Caribbean cancer patients, caregivers, and clinicians contribute questions that compound into community intelligence. Analyzing these patterns to characterize community learning and improve navigation quality is the purpose for which the ledger was created. The waiver enables research that directly serves the community that generated the data.

0.4. 4. Investigator Commitment

The investigators commit to the following:

1. No attempt will be made to re-identify any subject.

2. No individual question will be attributed to an identifiable person in any publication.
3. Any change to the data schema that would introduce identifiable information will be reported as a protocol modification requiring new IRB review and new consent procedures.
4. The terms of service disclosure regarding community learning will be maintained on all TALK instances.

0.5. 5. Signatures

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

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