

Always-on sensing cannot be discharged by a signature on a widely drafted consent form: it requires **four separate records**, each made before the first recording.

A lawful basis that is not the trial consent; a written justification for every stream; a stop mechanism built and tested; a plan for abnormal findings. **A study that cannot produce those four records is exposed to a refused or conditioned ethics approval, unlawful processing of health data, and an inspection finding on consent.**

THE PICTURE Each concern has an article — lawful basis is the one most misread

Concern	Regulatory anchor	What the design must do
Specific, informed consent	CTR Arts 29, 28(1)(c); E6(R3) s.2.8.10; FDA DHT guidance IV.F.3	State the always-on reality and any secondary use in the consent text
Right to withdraw	CTR Art. 28(3); E6(R3) s.2.9.1; FDA 2008 guidance; GDPR 7(3), 17(3)	Build and test a stop; state the retention position in consent
Data minimization	GDPR Arts 5(1)(b)–(c) and 25	Justify each stream against purpose; drop streams without one
Lawful basis and special-category data	GDPR Arts 6(1), 9(1)–(2), 35; EDPB Opinion 3/2019	Record Art. 6 basis, Art. 9(2) condition and DPIA before collection
Ethics oversight	21 CFR Part 56 or CTR Chapter III; FDA DHT guidance s.IV.H.1	Submit necessity, burden and the incidental-findings plan for review

Provisions cited as they stand at 1 September 2026; which applies to a given monitoring design, and how, is a matter for structured assessment with ethics and data-protection input.

QOINTA'S POSITION 'They consented' answers the wrong question

Consent is not the legal basis — and must still be specific

The EDPB has said CTR consent 'must not be confused' with GDPR consent and is rarely the right basis; sponsors rely on Art. 6(1)(c), (e) or (f) with an Art. 9(2)(i) or (j) condition.

Withdrawal stops collection; it does not erase the record

CTR Art. 28(3), FDA's 2008 retention guidance and GDPR Art. 17(3) all retain lawfully collected data. Offering deletion as a free choice promises what a regulated trial cannot deliver.

Convenience is not proportionality

That a stream is easy to collect passively says nothing about whether it is necessary. Collecting more than the purpose needs breaches GDPR Art. 5(1)(c) — it is not a richer dataset.

Passive sensing surfaces findings the protocol never sought

FDA expects the safety monitoring plan to address abnormal measurements and when participants are told; neither ICH E6(R3) nor the Declaration of Helsinki covers incidental findings.

FIVE DECISIONS, EACH MADE BEFORE THE FIRST RECORDING

- 1 Define what is collected** — exactly which streams run continuously, at what granularity, and for what stated purpose; drop the rest.
- 2 Fix the legal basis** — record the Art. 6 basis and Art. 9(2) condition, with a DPIA, before collection starts.
- 3 Make consent meaningful** — state what runs continuously, the uses and the retention position in the consent form.
- 4 Design real withdrawal** — a stop the participant triggers without the recruiter, that reaches the device, and logs when collection ended.
- 5 Plan incidental findings** — agree in advance how clinically significant signals are handled and returned, and disclose it in consent.

Read with care. The stop must reach the device — firmware, app or gateway upload — not only the database. On a participant's own handset, reading terminal-equipment data engages the ePrivacy rules; US state privacy statutes are unverified.

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Summary of QPP-22 1.0 — the full paper, with sources and figures, is published at qointa.com.

CTR Arts 28, 29, Chapter III · ICH E6(R3) s.2.8.10, 2.9.1 · GDPR Arts 4(11), 5, 6, 7(3), 9, 17(3), 25, 35 · EDPB Opinion 3/2019 · FDA DHT guidance s.IV.F.3, IV.H.1 · FDA retention guidance (2008) · 21 CFR Parts 50, 56

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