

When the Instrument Is Their Own Phone

A paper about the participant's position on a bring-your-own-device trial — written for the sponsor, sites and vendors who must discharge the obligations that anchor to them

Prepared for	Sponsors, sites, eCOA / ePRO vendors and the human-factors and data-protection functions.
Subject	The obligations that anchor to the participant and their own device on a BYOD design, and the evidence the study team must hold.
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Prepared by	Rudiger Mees

Executive summary

The answer. On a bring-your-own-device (BYOD) design the participant and their own phone become part of the instrument — and every obligation that follows anchors to the person, not to hardware the trial owns. The study team, not the participant, discharges them.

What that means in practice. Four duties attach to the participant: usability on the handset they actually hold; valid, informed eConsent bound to the right person; lawful and transparent processing of what is, in every trial, special-category health data; and attribution of every entry, including when a carer assists.¹ One hard rule sits beneath all four: where a trial relies on participants' own devices, a sponsor-provided alternative must be available so that people without a suitable phone are not excluded.²

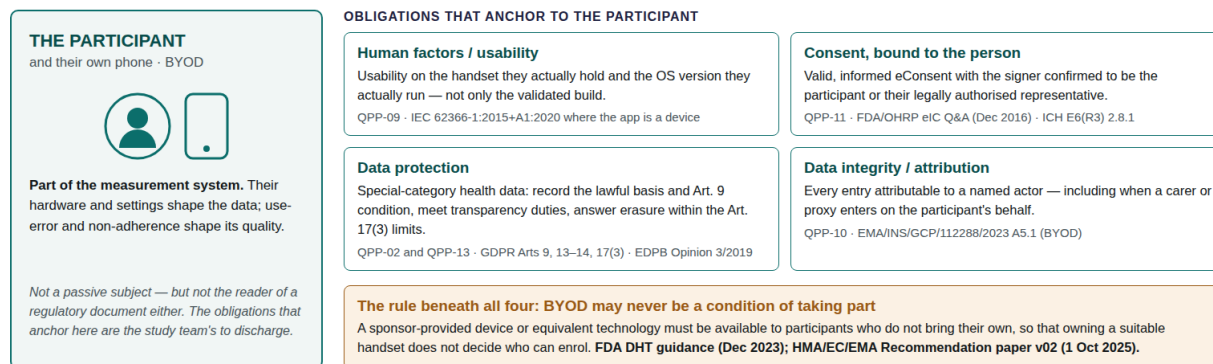
What to do. Design for the real device, the real behavior and the real rights, and the data stays analysable and attributable. Skip it and the loss arrives as missing entries, contested attribution and a consent record that cannot be defended at inspection. Figure 1 maps the obligations; Figure 2 locates the participant in the series' perimeters.

¹ Regulation (EU) 2016/679 (GDPR) Art. 9(1): data concerning health are a special category; processing in a clinical trial will normally rest on Art. 6(1)(c)/(e)/(f) with Art. 9(2)(i)/(j) rather than consent — EDPB, Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation and the GDPR (23 January 2019).

² FDA, Digital Health Technologies for Remote Data Acquisition in Clinical Investigations (final guidance, December 2023): "Sponsor-provided DHTs or other technologies to support their operation should be available as an option to ensure that participants who do not bring their own are not excluded." HMA/EC/EMA, Recommendation paper on decentralized elements in clinical trials, Version 02 (1 October 2025): the sponsor should provide alternatives if a participant is unable or unwilling to use their own private device.

Four obligations anchor to the participant — and the study team, not the participant, discharges every one

On a BYOD design the person and their own phone are part of the instrument. The duties attach to the person; the evidence is the trial team's to hold.



Design for the real device, the real behavior and the real rights, and the data stays analysable and attributable.

Illustrative composite — which obligations bite on a given BYOD design is a matter for structured assessment with human-factors and data-protection input.

Figure 1 — Four obligations anchor to the participant, and the study team — not the participant — discharges every one. *Illustrative composite — not a specific study.*

1. BYOD moves the instrument into the participant's hands, and the duty to account for it stays with the study team

This is a companion edition of qointa's position-paper series, read from the participant's position. When the instrument is the participant's own handset (BYOD), their device, settings and behavior become part of the measurement — and the consent, data-protection and usability obligations anchor to them.

It is written for the **sponsor, sites and vendors** who must discharge those obligations; the participant is its subject, not its reader. The series' central **"one device, several perimeters"** view (Figure 2) locates them: on BYOD the person and their own phone are the instrument at the core, and every perimeter anchors to that core.

Figure 2 — One device, several perimeters

The series' central view. On BYOD the participant and their own phone are the instrument at the core — and the perimeters that anchor to them are the study team's to honour.

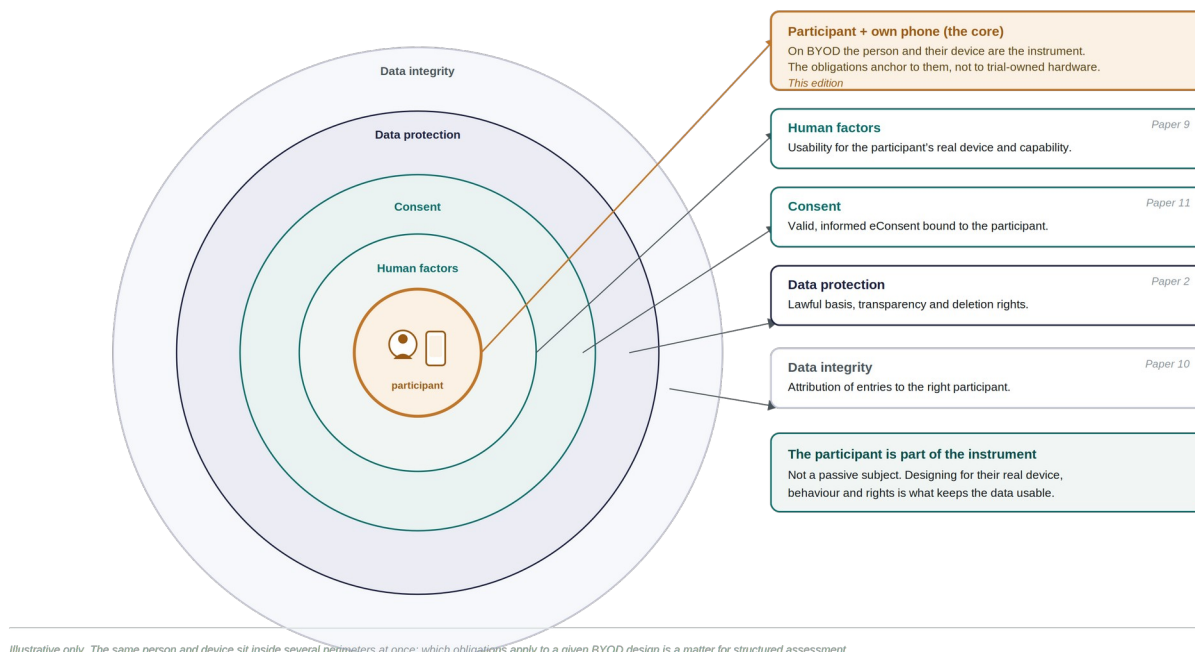


Figure 2 — On BYOD the participant and their own phone form the core the perimeters anchor to. Illustrative composite — not a specific study.

2. Four obligations anchor to the participant, and none of them can be delegated to them

- **Their device is part of the instrument.** On BYOD, the participant's hardware and settings shape the data.
- **Their behavior shapes data quality.** Use-error and non-adherence become missing or wrong data.
- **Their data and rights anchor here. Lawful basis, transparency and the data-subject rights attach to the person — but erasure only within the limits trial law sets.**³
- **Their consent must be valid, informed and bound to them. Identity is the weak point when consent is electronic and remote.**⁴

3. Each perimeter names a study-team action and the evidence that discharges it

Each perimeter is an obligation that anchors to the participant and is the study team's to discharge. The third column names the **study-team action and the evidence** that does so — what the team does, and what a

³ GDPR Art. 17(3)(b) and (d) disapply the right to erasure where processing is necessary for compliance with a legal obligation or for scientific-research purposes under Art. 89(1); Regulation (EU) 536/2014 Art. 28(3): withdrawal of consent does not affect activities already carried out or the use of data obtained before withdrawal. EDPB Opinion 3/2019 (23 January 2019): data are erased only where no other lawful basis justifies retention.

⁴ FDA and OHRP, Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers (December 2016): the system must include a method to ensure that the person electronically signing the consent is the participant or their legally authorised representative. ICH E6(R3) 2.8.1: the investigator should assure themselves of the identity of the participant or legally acceptable representative, whether consent is taken in person or remotely.

GCP inspector or ethics committee would expect to see. The consent row is flagged because identity is where remote, electronic consent most often fails.

Perimeter / topic	What it means for the participant	Study-team action and evidence	Series paper
Human factors	Usability for the participant's real device and capability.	Test usability across the real device and OS range, not only the validated build; offer a sponsor-provided device to anyone without a suitable handset.	QPP-09
Consent	Valid, informed eConsent bound to the participant.	Evidence valid, informed eConsent bound to the right person , incl. remote identity.	QPP-11
Data protection and privacy	Lawful basis, transparency and data-subject rights over special-category health data.	Record the lawful basis and the Art. 9 condition; meet the Art. 13–14 transparency duties; handle erasure requests within the Art. 17(3) limits.	QPP-02 and QPP-13
Data integrity	Attribution of entries to the right participant.	Evidence attribution, including for assisted or proxy entry.	QPP-10

4. Three BYOD facts break the standard design: device diversity, data on a phone the trial never owned, and assisted entry

- **Device diversity.** The interface you validated is not the one every participant sees, and the handset you did not choose sets the floor for data quality.
- **Trial data left on a personal device.** In qointa's assessment, storage limitation under GDPR Art. 5(1) (e) makes clearing trial data from a handset the trial never owned part of close-out — a different question from the participant's erasure right, and one QPP-13 — Decommissioning, Retention and Disposal sets out.
- **Assisted or proxy entry.** When a carer enters data, the audit trail must show who acted — which the standard self-entry model does not.

5. Six checks make the participant-anchored obligations auditable

A short, repeatable checklist for discharging the obligations that anchor to the participant — so the resulting data stays **usable and attributable**.

Checklist item	Evidence that it is done
Usability tested across real participant devices.	Human-factors evidence beyond the validated build.
eConsent is valid, informed and identity-bound.	Remote eConsent records tied to the right participant.
Lawful basis and transparency recorded.	Data-protection notice and lawful-basis documentation.
Data clearance from the personal device at close-out is planned.	Process to clear trial data from a device not retained.

Checklist item	Evidence that it is done
Attribution handles assisted / proxy entry.	Rules and records for who entered data, and how.
A sponsor-provided alternative is offered to participants without a suitable device.	Provisioning route and uptake recorded, with a representativeness assessment of who BYOD would otherwise exclude (QPP-17 — Representativeness and Equitable Access).

BYOD consent & usability considerations (illustrative)

Design questions to resolve before a BYOD study opens:

- **Identity and remote consent:** How is the consenting person confirmed to be the participant when consent is electronic and remote?
- **Device range:** Which real devices and OS versions are supported, and how is usability tested across them?
- **Assisted entry:** If a carer helps, how is the entry attributed and recorded?
- **Exit and data clearance:** How is trial data cleared from a personal device at close-out, and how is the participant told?

6. The participant's position runs across five papers in the series

How this edition fits the qointa series

This edition reads the series from the participant's position. The obligations that anchor to them sit across these papers:

- **QPP-09 — Human Factors.** Usability for the participant's real device and capability, not the validated build.
- **QPP-11 — eConsent.** Valid, informed consent bound to the participant, especially when remote.
- **QPP-02 — Data Residency and Cross-Border Transfer.** Where participant data go once they leave the handset, and under whose law.
- **QPP-10 — Device-Side Data Integrity.** Attribution of entries to the right participant, including proxy entry.
- **QPP-17 — Representativeness and Equitable Access.** BYOD burden and device access can exclude participants — a representativeness question.
- **QPP-22 — Continuous Monitoring, Consent and Participant Burden.** What continuous collection asks of the person carrying the phone.
- **QPP-13 — Decommissioning, Retention and Disposal.** Clearing trial data from a device the trial never owned, and what is retained.

Regulatory basis

This edition summarizes the position set out in QPP-09 — Human Factors, QPP-10 — Device-Side Data Integrity, QPP-11 — eConsent, QPP-13 — Decommissioning, Retention and Disposal and QPP-17 — Representativeness and Equitable Access; the sources are cited there in full.

The load-bearing sources for the BYOD position are:

- FDA, Digital Health Technologies for Remote Data Acquisition in Clinical Investigations (final

guidance, December 2023) — s.III (verification and validation of the DHT for the population and platforms used); sponsor-provided technology to be available so that participants who do not bring their own are not excluded.

- HMA/EC/EMA, Recommendation paper on decentralized elements in clinical trials, Version 02 (1 October 2025) — alternatives where a participant is unable or unwilling to use a private device; identity checks for remote consent.

- EMA, Guideline on computerised systems and electronic data in clinical trials (EMA/INS/GCP/112288/2023, adopted 7 March 2023) — Annex 4 (security) and Annex 5 A5.1 (participants' own devices), A5.3 (eConsent).

- ICH E6(R3) Principles and Annex 1 (Step 4, 6 January 2025; EU effective 23 July 2025) — 2.8 informed consent, including confirmation of the participant's identity; Annex 2 (Step 4, 3 June 2026; EU effective 15 January 2027).

- FDA and OHRP, Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers (December 2016) — the signer must be confirmed as the participant or their legally authorised representative.

- Regulation (EU) 2016/679 (GDPR) — Arts 5(1)(e), 9(1) and 9(2)(i)–(j), 13–14, 17(3)(b) and (d), 89(1); EDPB, Opinion 3/2019 on the interplay between the Clinical Trials Regulation and the GDPR (23 January 2019).

- Regulation (EU) 536/2014 (Clinical Trials Regulation) — Art. 28(3): withdrawal does not affect activities already carried out or the use of data obtained before withdrawal.

7. Four actions keep BYOD data usable

On a BYOD design the participant is part of the measurement system, and the obligations that anchor to them are the study team's to discharge. **Four actions keep the resulting data usable.**

- **Test usability on real devices** so the interface each participant actually sees is the one you validated against.
- **Bind eConsent to the right person** so remote, electronic consent is valid and informed, not merely acknowledged.
- **Handle data rights accurately** — record the lawful basis and the Art. 9 condition, meet the transparency duties, and answer erasure requests within the limits Art. 17(3) and CTR Art. 28(3) set.
- **Resolve attribution up front** so assisted or proxy entry never leaves data attributed to the wrong person.
- **Offer a sponsor-provided device** so that owning a suitable handset is never a condition of taking part.

Example statement for the study team

A short, defensible framing a study team can record for a BYOD design:

“On this BYOD study the participant and their own device are part of the instrument. We test usability across the real device range, bind eConsent to the verified participant including when remote, record the lawful basis and Art. 9 condition, meet the transparency duties and answer erasure requests within

the limits trial law sets, and define attribution rules for assisted or proxy entry. We offer a sponsor-provided device to anyone without a suitable handset, and we have assessed and recorded who BYOD would otherwise exclude.”

Scope and status. This is a companion edition summarizing qointa's position-paper series from one stakeholder's perspective, keyed to Section 12 of the Regulatory Impact Assessment (QPP-00). It summarizes the position set out in the numbered papers, where the sources are cited in full. It is not legal advice; the detail and the current framework references live in the numbered papers, and any specific position should be confirmed with qualified regulatory counsel.