

What an Ethics Committee Can Require

A companion reading on the ethics-committee lens — written for the sponsors, CROs and study teams who prepare the submission

Prepared for	Sponsors, CROs and the teams preparing clinical-trial and IRB submissions for DHT studies.
Subject	What an IRB or ethics committee can require of a DHT study, which instrument makes it binding, and the evidence a submission should already hold.
Status / Date	Final — 1 September 2026
Version	1.0
Prepared by	Rudiger Mees

Executive summary

The answer. Prepare the device and consent evidence before the submission, because an ethics committee's remit reaches further into a DHT study than most teams plan for — and the instrument that follows a question is a condition of approval, not a conversation.¹

What a committee can require. Consent is its center of gravity: the eConsent content and process, including the remote elements, are reviewed and approved.² Usability, device suitability and the safeguards for vulnerable participants sit squarely inside the approval criteria. In the United States the committee also makes the significant-risk / non-significant-risk determination for an investigational device — the single most concrete thing it can require about the device itself.³

What to do. A question becomes enforceable when it is written down — as a condition of approval or a required modification in the US, or through the single Member State decision and the CTIS request-for-information process in the EU.⁴ Holding the evidence at submission is cheaper than producing it mid-study under a modification — that is qointa's commercial judgment, not a regulatory requirement.

¹ US: 21 CFR 56.109(a) — an IRB “shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities”; approval criteria at 21 CFR 56.111, including (a)(7) adequate provisions to protect privacy and maintain the confidentiality of data; continuing review at least annually and the power to suspend or terminate approval at 56.109(f) and 56.113.

² FDA and OHRP, Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers (December 2016): the IRB must review and approve the electronic informed consent and any amendments the participant will receive and view. ICH E6(R3) 1.2.2. HMA/EC/EMA, Recommendation paper on decentralized elements in clinical trials, Version 02 (1 October 2025): the consent procedure should be described step by step in the clinical trial application to allow ethical review.

³ 21 CFR 812.66 and 812.2(b)(1)(ii): if an IRB determines that a study presented as non-significant-risk involves a significant-risk device, it notifies the investigator and, where possible, the sponsor, and the study may not begin except under 21 CFR 812.30(a).

⁴ Regulation (EU) 536/2014: the ethics assessment feeds a single Member State decision, with Part II assessed nationally; requests for information reach the sponsor through CTIS. National ethics-committee law governs composition and procedure.

A committee's question is not yet binding — what binds is the condition of approval it is written into

Left: four areas a DHT study should expect to be asked about, and the evidence that answers each. Right: the instruments that turn a question into a requirement.

Consent Is the eConsent content and process approved, including the remote elements? Approved materials, version control, a re-consent plan, documented identity and comprehension safeguards.	WHAT MAKES IT BINDING — THE LEGAL INSTRUMENT US · approval, or a required modification An IRB reviews and has authority to approve, require modifications in order to secure approval, or disapprove. The approval criteria include privacy and confidentiality of data. 21 CFR 56.109(a); 56.111, incl. (a)(7)
Human factors Can the actual population — including vulnerable participants — use it reliably and safely? Usability and use-safety evidence in the real population, with assent and representation provisions where they apply.	US · continuing review and suspension Approval is reviewed at least annually, and can be suspended or terminated. Additional safeguards apply to vulnerable participants. 21 CFR 56.109(f); 56.113; 56.111(b)
Device suitability Is the device fit for its role, and does it make this a significant-risk study? A suitability assessment tying role to conditions, and the risk determination the committee is asked to make.	US · the SR / NSR determination If the IRB finds that a study presented as non-significant-risk involves a significant-risk device, it notifies sponsor and investigator and the study may not begin without an IDE. 21 CFR 812.66; 812.2(b)(1)(i); 812.30(a)
Data integrity Does device-side integrity support participant rights and safety? Attribution, audit trail and time-source evidence for the data the participant generates.	EU · the single decision The ethics assessment feeds one Member State decision; requests reach the sponsor through the CTIS request-for-information process, with Part II assessed nationally. Regulation (EU) 536/2014, Parts I and II
An unrecorded expectation binds nothing A question, or an expectation voiced in a meeting, is not yet a requirement. It becomes enforceable when it is written down — as a condition of approval or a required modification in the US, or through the single Member State decision and the RFI process in the EU. Prepare for the question; comply with the condition.	

Have the evidence before the question: a prepared submission costs less than a mid-study modification.

Illustrative composite — not a specific study. What a given committee requires turns on the study, the population and the jurisdiction.

Figure 1 — A committee's question is not yet binding; the condition of approval it is written into is. Illustrative composite — not a specific study.

1. A committee's remit reaches the device, not only the consent form

This is a companion edition of qointa's position-paper series, read through the ethics-committee lens. A committee can require evidence of device suitability, usability, consent and the handling of participant data before a study opens and during it — and in the United States it decides whether an investigational device makes the study a significant-risk one.

It is written for sponsors, CROs and the teams preparing the submission. The series' central “one device, several perimeters” view (Section 3) locates the committee: ethics review reaches across the participant-facing perimeters and can require evidence in any of them.

2. Four things a DHT study should expect to be asked to evidence

- **The remit covers the device, not only the paperwork.** Suitability, usability and the protection of participant data are inside the approval criteria; device-side audit trail and time source are primarily a GCP and computerized-systems matter for the sponsor and the inspectorate, and a committee may reach them through the rights-and-safety limb rather than as of right.
- **Consent is its center of gravity. The eConsent content and process, including the remote elements, are reviewed and approved before use and on amendment.**
- **Vulnerable participants raise the bar.** Additional safeguards are an explicit approval criterion, and assent and representative-consent arrangements are reviewed with the rest of the consent materials.

⁵ 21 CFR 56.111(b) (additional safeguards where some or all participants are vulnerable); 21 CFR 50 subpart D (50.50 IRB duties; 50.55 assent and parental permission); ICH E6(R3) 1.2.1 and 1.3.7; Regulation (EU) 536/2014 Arts 31 and 32.

- **What binds is the condition, not the question.** An expectation voiced in a meeting requires nothing; a condition of approval, a required modification or a national decision does — and it is enforceable through continuing review and the power to suspend approval.

3. Each perimeter carries a predictable question and a piece of evidence that answers it

Each perimeter carries a question a DHT study should expect. The third column names the **question and the evidence that answers it** — what a committee typically asks, and what a prepared submission already contains. Consent is flagged because it is the committee's center of gravity and the perimeter where remote delivery most often creates a gap.

Perimeter / topic	What the committee reviews	Typical committee question / evidence	Series paper
Consent	eConsent content, process, version control and re-consent.	"Is eConsent valid and informed, including remote?" — approved materials, version control, re-consent plan.	QPP-11
Human factors	Usability and use-safety for the actual population.	"Can the real population use it safely?" — usability / use-safety evidence.	QPP-09
Device suitability	Evidence the device is fit for its role in the study.	"Is the device fit for its role — and is this a significant-risk study?" — a suitability assessment tying role to conditions, and the SR / NSR determination (21 CFR 812.66).	QPP-00, QPP-01
Data integrity	Device-side integrity supporting participant rights and safety.	"Does device-side integrity protect rights?" — device-side integrity evidence.	QPP-06, QPP-10

4. Three things sink DHT submissions: a formalistic consent, an unchecked signature route, and no population evidence

- **Treating eConsent as a formality.** Consent-process gaps are among the most serious findings a GCP inspection raises — though not, on the published EU data, the most common: informed consent accounted for 28 of 720 findings in the EMA GCP Inspectors Working Group's 2023 annual report.⁶
- **Remote consent without safeguards.** Identity and comprehension must be designed in, not assumed.
- **Whether the signature route is accepted at all.** Electronic signature on consent is a matter of national law: several Member States require a qualified electronic signature, others accept an advanced signature, and some decide case by case — and OHRP permits an electronic signature only where it is legally valid in the jurisdiction. Confirm the route, including for a legally authorised representative, before the system is built.⁷

⁶ EMA, Annual report of the Good Clinical Practice Inspectors Working Group 2023: informed consent, 28 of 720 findings (3.9%); the largest categories were General (40%), Trial Management (19.2%) and Investigational Site (11.9%). Ethics committees do not issue inspection findings.

⁷ HMA/EC/EMA, Recommendation paper on decentralized elements in clinical trials, Version 02 (1 October 2025), national-provisions annex. FDA and OHRP, Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers (December 2016).

- **Vulnerable-participant designs without provisions. Additional safeguards are an approval criterion, not a courtesy — see Stakeholder Edition S14 — Paediatric and Vulnerable Participants.**

5. Seven checks make a DHT submission answerable on the day it is filed

A short, repeatable checklist for preparing a submission that anticipates the committee's questions — so an expectation is **met before it is asked**.

Checklist item	Evidence that it is done
eConsent materials and process are submission-ready.	Approved content, version control and a re-consent plan.
Remote-consent safeguards are designed in.	Identity verification and comprehension checks documented.
The electronic-signature route is confirmed acceptable in each country.	National-law check on the electronic-signature route, including for a legally authorised representative.
Usability evidence covers the real population.	Human-factors / use-safety results for the actual users.
Device suitability is assessed and recorded.	Suitability assessment tying role to conditions, and — in the US — the SR / NSR determination under 21 CFR 812.66.
Device-side data-integrity evidence is held.	Device-side integrity supporting rights and safety.
Vulnerable-population provisions are in place.	Assent, representation and usability provisions documented.

Common committee requests (examples)

Requests a DHT study should expect. The wording is qointa's illustration of the form these requests take — not a quotation from any committee:

- **Consent:** *"Show the eConsent flow, including how remote identity and comprehension are confirmed."*
- **Signature:** *"Confirm whether the electronic signature is acceptable under national law here, or whether a wet-ink signature is required."*
- **Usability:** *"Provide use-safety evidence for the actual population, including any vulnerable groups."*
- **Suitability:** *"Evidence the device is fit for its role, and how phone-side integrity protects participants."*

6. The committee's questions map onto six papers in the series

How this edition fits the qointa series

This edition reads the series through the ethics-committee lens. The committee's questions map onto

these papers:

- **QPP-11 — eConsent.** The committee's central concern: valid, informed consent, including remote elements.
- **QPP-09 — Human Factors.** Usability and use-safety for the actual population, scrutinized harder for vulnerable groups.
- **QPP-00, QPP-01 — Regulatory Impact Assessment (RIA) and Endpoint Validation.** The structured assessment of the device's role in the study, and the evidence that the measure it produces is valid.
- **QPP-06, QPP-10 — Inspection-Readiness and Device-Side Data Integrity.** The device-side evidence that supports participant rights and safety.
- **Stakeholder Edition S14 — Paediatric and Vulnerable Participants.** The additional safeguards a committee reviews under 21 CFR 56.111(b) and CTR Arts 31–32.
- **QPP-17 — Representativeness and Equitable Access, and QPP-22 — Continuous Monitoring, Consent and Participant Burden.** Who a DHT design excludes, and what continuous collection asks of the participant — both squarely ethics-committee questions.

Regulatory basis

This edition summarizes the position set out in QPP-09 — Human Factors, QPP-11 — eConsent and QPP-00 — Regulatory Impact Assessment (RIA); the sources are cited there in full. The load-bearing sources for the ethics-review position are:

- 21 CFR 56.109(a) and (f), 56.111 (approval criteria, incl. (a)(7) privacy and confidentiality) and 56.113 (suspension or termination of approval) — the source of a US IRB's power.
- 21 CFR 812.66 with 812.2(b)(1)(ii) and 812.30(a) — the IRB's significant-risk / non-significant-risk determination for an investigational device.
- 21 CFR 50 subpart D (50.50, 50.55) and 56.111(b) — assent, parental permission and additional safeguards for vulnerable participants.
- Regulation (EU) 536/2014 — Part I / Part II assessment and the single Member State decision; Arts 31 and 32 (incapacitated participants and minors). National law governs ethics-committee composition and procedure.
- ICH E6(R3) Principles and Annex 1 (Step 4, 6 January 2025; EU effective 23 July 2025) — s.1 (IRB/IEC review, incl. 1.2.2 consent materials and 1.3.7 assent) and s.2.8 (informed consent).
- FDA and OHRP, Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers (December 2016) — IRB review of eConsent; electronic signature only where legally valid in the jurisdiction.
- HMA/EC/EMA, Recommendation paper on decentralized elements in clinical trials, Version 02 (1 October 2025) — the consent procedure described step by step for ethical review; national annex on electronic-signature requirements.
- EMA, Annual report of the Good Clinical Practice Inspectors Working Group 2023 — the published distribution of GCP inspection findings.

7. Four questions to answer before the committee asks them

Anticipating what a committee can require — on consent, usability, device suitability and vulnerable participants — turns a mid-study modification into a prepared submission. **Answer these four before the committee asks them.**

- **Is eConsent valid, informed and identity-bound?** Including remote elements and a re-consent plan.
- **Is the signature method acceptable here?** Confirm the electronic-signature route under national law in each country, including for a legally authorised representative.
- **Can the real population use it safely?** Usability and use-safety evidence, with closer scrutiny for vulnerable groups.
- **Is the device fit for its role, with integrity protected?** A suitability assessment and device-side integrity evidence.
- **Is this a significant-risk study?** In the US, the IRB's SR / NSR determination under 21 CFR 812.66 decides whether an IDE is needed before the study may begin.

Example submission-readiness statement

A short, defensible framing a team can bring to the committee:

"Our submission anticipates the committee's lens: eConsent materials, version control and a re-consent plan are provided, with remote identity and comprehension safeguards designed in and the electronic-signature route confirmed acceptable under national law in each participating country. We include use-safety evidence for the actual population, a device-suitability assessment, and phone-side integrity evidence — so that what the committee may require is already in hand."

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 describes qointa's reading of published requirements and does not represent the view of any ethics committee or regulator. 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.