

Prepare the device and consent evidence **before the submission**: a committee's remit reaches further into a DHT study than most teams plan for.

Consent is the committee's center of gravity, but usability, device suitability and safeguards for vulnerable participants sit inside the approval criteria — and in the US the IRB makes the SR / NSR determination. **A question becomes enforceable once written into a condition of approval; hold the evidence at filing.**

THE PICTURE Each perimeter carries a predictable question and the evidence for it

Perimeter	Typical committee question	Evidence a prepared submission holds
Consent	"Is eConsent valid and informed, including remote?"	Approved materials, version control, re-consent plan, signature route
Human factors	"Can the real population use it safely?"	Usability / use-safety evidence for the actual users
Device suitability	"Is the device fit for its role — is this significant-risk?"	Suitability assessment; the SR / NSR determination (21 CFR 812.66)
Data integrity	"Does device-side integrity protect rights?"	Device-side integrity evidence supporting rights and safety

Consent is flagged because remote delivery most often creates a gap there. Question wording is qointa's illustration of the form requests take — not a quotation from any committee.

QOINTA'S POSITION Four things a DHT study should expect to be asked to evidence

The remit covers the device, not only the paperwork

Suitability, usability and protection of participant data are inside the approval criteria; device-side audit trail and time source are primarily a GCP matter a committee may reach via rights and safety.

Consent is its center of gravity

The eConsent content and process, including the remote elements, are reviewed and approved before use and on amendment. Identity and comprehension must be designed in, not assumed.

Vulnerable participants raise the bar

Additional safeguards are an explicit approval criterion, not a courtesy; assent and representative-consent arrangements are reviewed with the rest of the consent materials.

What binds is the condition, not the question

An expectation voiced in a meeting requires nothing; a condition of approval, required modification or national decision does — enforceable through continuing review and suspension.

SIX QUESTIONS TO ANSWER BEFORE THE COMMITTEE ASKS THEM

- 1 Make eConsent valid, informed and identity-bound** — including remote elements, version control and a re-consent plan.
- 2 Confirm the signature route under national law** in each country — qualified, advanced or case by case — incl. for a legal representative.
- 3 Evidence that the real population can use it safely** — usability and use-safety results for the actual users, harder for vulnerable groups.
- 4 Assess and record device suitability** — a suitability assessment tying role to conditions, plus device-side integrity evidence.
- 5 Settle the SR / NSR determination early** — in the US, the IRB's call under 21 CFR 812.66 decides whether an IDE is needed first.
- 6 Document vulnerable-population provisions** — assent, representation and usability provisions, per Stakeholder Edition S14.

28 of 720

GCP inspection findings on informed consent — EMA GCP IWG annual report 2023

21 CFR 812.66

the IRB's SR / NSR determination — its most concrete requirement of the device

Read with care. That holding the evidence at submission is cheaper than producing it mid-study is qointa's commercial judgment, not a regulatory requirement. This is qointa's reading of published requirements, not any committee's view.

READ NEXT

QPP-11 eConsent · QPP-09 Human Factors · QPP-00 RIA · QPP-01 Endpoint Validation · QPP-06 Inspection-Readiness · QPP-10 Data Integrity · QPP-17 · QPP-22 · Stakeholder Edition S14



Summary of S12 1.0 — the full paper, with sources and figures, is published at qointa.com.

21 CFR 56.109, 56.111, 56.113 · 21 CFR 812.66, 812.2(b)(1)(ii), 812.30(a) · 21 CFR 50 subpart D · Regulation (EU) 536/2014 Arts 31–32 · ICH E6(R3) s.1, s.2.8 · FDA/OHRP eConsent Q&A (2016) · HMA/EC/EMA DCT paper v02

© qointa 2026 – Public – Uncontrolled when printed · Not legal advice; this summary does not classify any device.

qointa · DHT governance for clinical trials
sales@qointa.com · qointa.com