

A DHT design validated in general adults cannot be carried across to children or adults lacking capacity without adding evidence at every perimeter at once.

The population is a multiplier, not a footnote: usability, consent, data protection and data quality all rise together, and every rise has a rule behind it. **Settle the additions in the design, not at submission — discovering the gap at ethics review, or in data that cannot be analyzed, costs far more.**

THE PICTURE The perimeters do not change; the evidence each one demands does

Perimeter	How it intensifies	Evidence needed
Human factors	Reduced vision, dexterity, literacy or developmental stage; a carer	Usability studies in the target population and with carers
Consent	Representative consent (EU) or parental permission (US); assent	Consent model by age and capacity band; re-consent at legal competence
Data protection	Children's data need additional conditions and safeguards	Children's-data safeguards with a DPIA (GDPR Art. 35); COPPA / ICO
Endpoint validation	Healthy-adult measures may not hold in the target population	Re-validation in the actual population (ICH E11(R1) / E11A)
Data integrity	Carer-assisted or proxy entry raises attribution questions	An attribution model for proxy entry: who acted, in the audit trail

Human factors is flagged because use-error and missing data concentrate there. Who counts as vulnerable is defined in ICH E6(R3) and is wider than these examples — capacity, not age, is the test.

QOINTA'S POSITION Vulnerability raises four obligations at once; the consent rule varies

The population is a multiplier, not a footnote

Vulnerability raises the obligation across usability, consent, data protection and data quality at the same time — a general-adult design cannot simply be pointed at a vulnerable one.

Consent is rebuilt by age and capacity band

EU: the legally designated representative consents, the minor takes part, refusal is respected, re-consent at legal competence. US: parent or guardian permits; child assents where capable.

Children's data attract additional safeguards

Health data are special-category for every participant; specific here are additional protection, a DPIA, and — outside the EU — COPPA in the US and the ICO Children's Code in the UK.

A carer or proxy breaks the attribution model

A third party operating the device or entering data breaks the assumption that the person who acted is the participant — it touches consent, data integrity and usability at once.

SIX MOVES TURN THE HIGHER BAR INTO A DESIGN A COMMITTEE CAN APPROVE

- 1 Test usability with the real users** — the target population and their carers, not a healthy-adult stand-in.
- 2 Build the consent model by capacity band** — representative consent or parental permission, assent where required, re-consent at competence.
- 3 Settle the children's-data plan up front** — lawful basis, additional safeguards, a DPIA, and COPPA or the ICO Code where they apply.
- 4 Re-validate endpoints in the population** — do not assume a healthy-adult measure transfers.
- 5 Design the proxy attribution model** — a recorded answer to who acted, in the audit trail.
- 6 Bring the safeguards to the committee early** — surface usability, consent and attribution plans in design, not at submission.

Read with care. Requirements for these populations are jurisdiction- and ethics-committee-specific. COPPA's application to non-commercial research is fact-specific. The use-error concentration claim is qointa's assessment, not a cited finding.

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Summary of S14 1.0 — the full paper, with sources and figures, is published at qointa.com.

Regulation (EU) 536/2014 Arts 10, 31, 32 · 21 CFR 50 subpart D, 56.111(b) · ICH E6(R3) s.2.8 · ICH E11(R1), E11A · GDPR Recital 38, Arts 8, 9(1), 35 · EDPB Opinion 3/2019 · COPPA Rule (90 FR 16902) · ICO Children's Code

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