



DECEMBER 2025

Highlights from ICH E6 (R3) GCP Guideline

**ICH E6 (R3) GCP Guidelines will take effect
from 1 January 2026 - Know what's changing now.**

WHAT'S NEW?



Roles & Accountability

- Define and document source records, data capture methods, storage locations, and delegation log upfront
- PI remains accountable with proportionate oversight, written service agreements with service providers, and adequate training



Flexible Study Conduct

- IP may be shipped to subject's location and administered at subject's home by site staff, subject, caregiver, or healthcare professional



Data Integrity & Computerised Systems

- Minimize transcription errors by reducing transfer steps between source and database
- Implement user access controls, report system incidents to sponsor/IRB and safeguard data from unauthorized access with proper audit trails and metadata



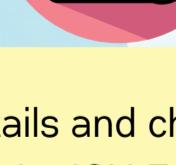
Informed Consent

- Flexible format where ICF can be paper or electronic using varied approaches (images, videos)
- New consent elements to include where applicable: Reasonable foreseeable risks to participant's partner, payment details and more.



Transparency & Archival

- Inform subjects about research results and treatment received when available from sponsor
- Ensure archived records remain available, accessible, readable, and protected from unauthorized access and accidental or premature destruction



For full details and changes, please refer to the ICH E6 (R3) GCP Guideline [here](#).

References: ICH E6 (R3) Good Clinical Practice Guideline
NHG Health PCR SOPs Summary of Changes (06 Nov 2025)

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*Disclaimer: Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/guidelines relating to the above.