Chicken Soup
for the Busy Coordinator

NHG Health

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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