ICH E6 (R3) GCP GUIDELINE UPDATES:

CLINICAL TRIAL START-UP

ICH E6 (R3) Good Clinical Practice (GCP) Guideline effective 1 Jan 2026:
Get compliant before starting your clinical trials

✅ DOCUMENTATION SETUP 📁

Prior to study initiation:

- Define & document type of source record(s) & location
- Establish data capture methods

⚠️ *Avoid unnecessary transcription between source records & data acquisition tools e.g.*

❌ *Paper → Paper → Electronic*
❌ *Multiple manual transfers*
❌ *Redundant data entry*

✅ STUDY TEAM DELEGATION

Create delegation log: 📋

- Verify team members are qualified
- Assign specific tasks for each member
- Document training
- Clinical practice activities may not require delegation, but documentation of departmental involvement & PI authorization is necessary.

⚠️ *Appoint supervisory staff for large teams*

⚠️ *PI Change = Create new Delegation Log*

✅ EMERGENCY UNBLINDING 🚨

Protect participant safety:

- Prepare for emergency unblinding from start of study per protocol without undue delay and hindrance
- Maintain unblinding information with risk mitigation (e.g. controlled access for authorized personnel only)

✅ SERVICE PROVIDER OVERSIGHT 🏢

PI is accountable:

To maintain proportionate oversight of 3rd party service providers based on data significance & participant safety risks:

- Have written service agreements defining roles, activities & responsibilities
- Maintain research conduct accountability
- Provide training and ensure record access to persons performing research activities

References:

- *ICH E6 (R3) GCP: Sections 2.3.1- 2.3.4, 2.11, 2.12.2*
- ***Updated NHG Health Proper of Conduct (PCR) SOPs*** *501- A02, A03, B02, B03, C02*
  - Summary of changes: NHG Health Proper Conduct of Research SOPs & Templates

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