



NDCT Rules, 2019 vs ICH GCP E6 (R3)

Aspect	NDCT Rules, 2019 (India)	ICH-GCP E6(R3)
Regulatory Authority	DCGI (CDSCO), Government of India	International Council for Harmonisation (ICH)
Applicability	Mandatory for all clinical trials conducted in India	Global standard adopted by regulators worldwide
Primary Focus	Regulatory control, participant protection, safety reporting	Ethical conduct, participant safety, data integrity
Ethics Committee (EC)	EC approval mandatory; EC must be registered	Independent Ethics Committee / IRB required
Informed Consent	Mandatory, documented, language understandable to participant	Mandatory, voluntary, documented, ongoing process
Participant Rights & Safety	Emphasizes safety, medical care, compensation for trial-related injury	Rights, safety, and well-being are paramount
Risk-Based Approach	Implicit through regulatory conditions	Explicit risk-proportionate trial controls
Protocol Compliance	Strict adherence to DCGI-approved protocol	Compliance with approved protocol and amendments
Investigator Responsibilities	Qualified investigators; PI oversight required	Qualified investigators; defined oversight and delegation
Safety Reporting (SAE)	Defined timelines (e.g., 14 calendar days)	Timely reporting per protocol and regulations
Compensation for Injury	Mandatory as per NDCT provisions	Addressed as per local regulations
Post-Trial Access	Required where applicable	Encouraged based on benefit and ethics
Data Integrity	Requires accurate and reliable data	ALCOA+ principles emphasized
Documentation	Essential documents required for inspections	Essential documents enable reconstruction of trial
Monitoring & Audits	DCGI inspections and regulatory audits	Sponsor monitoring, audits, regulatory inspections
Reporting Requirements	Six-monthly status reports; trial completion notification	Reporting as per protocol and regulations
Global Acceptance	India-specific regulatory framework	Globally accepted ethical and quality standard