

Summary

Document type	Purpose	Description
Protocol	Trial blueprint	A core regulatory document describing the objectives, design, methodology & statistical components of the trial
Investigator's Brochure	Product background and safety information	A regulatory and scientific document providing comprehensive data & background about the Investigational Product
Informed Consent Form	Participant consent	An ethical and regulatory document ensuring that trial participants are fully informed about the study and consent to participation
Case Report Form	Data collection	An operational tool used to systematically record trial data for each participant as specified in the protocol
Policies	Organizational principles	Highest level document that shows management's promise to maintain quality and guide the QMS.
Manuals	Quality guide	Explains the quality policy, goals, system scope, and how key procedures work together
Standard Operating Procedures	Operational consistency	Written steps that explain how to do routine tasks the same way every time to keep quality steady.
Work Instructions	Task specific guidance	Clear, step-by-step guidance showing how to do specific tasks within a procedure
Forms and Records	Evidence Documentation	Forms collect data consistently and records provide proof that quality processes and procedures were properly followed

Reference Guidelines

NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS dated 2017: [ICMR National Ethical Guidelines.pdf](#)

THE NEW DRUGS AND CLINICAL TRIALS RULES, 2019: As amended vide GSR 778(E) dated 14-10-2022, w.e.f. 14-10-2022 : [Circulars](#)

ICH HARMONISED GUIDELINE – GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R3) dated 06 Jan 2025: [ICH Official web site : ICH](#)

Recent Industrial Developments

The ICH E6(R3) guidelines adopted on January 6, 2025, update clinical trial standards by promoting a flexible and risk-based approach to how trials are conducted. For trial protocols, this means designing them to be "fit for purpose" with a focus on what is most important for quality and safety. Informed consent processes are enhanced to be clearer and more patient-focused. Case Report Forms become more flexible, relying more on digital tools for data collection. The Investigator's Brochure is also updated to align with the risk-based approach and flexibility principles, ensuring timely sharing of relevant safety information. Standard Operating Procedures must be clear, flexible and focused on managing risks to ensure trial quality and participant safety, adapting to new technologies and modern trial designs. This update aims to make clinical trials more efficient and participant-focused without compromising safety or data quality.

For more information, please refer to the guidelines using below link:

ICH Official web site : [ICH Official web site : ICH](#)