CLINICAL EXCELLENCE CONSULTING

Informed Consent in Clinical Research

Glossary • ICF Elements • Consenting Process • FDA Findings • Best Practices

Voluntary Process

Subject freely consents after full disclosure of trial details.

Patient Protection

IRB oversight ensures ethical safeguards for every participant.

Documentation

Written, signed, dated ICF required — no verbal consent alone.

Ongoing Compliance

Re-consent required for protocol amendments affecting subjects.

Key Glossary- ICH-GCP E6 (R3)

CONFIDENTIALITY	Prevention of unauthorized disclosure of sponsor data or subject identity
INFORMED CONSENT	Voluntary process confirming subject willingness — written, signed, dated
IMPARTIAL WITNESS	Independent observer present when subject cannot read the ICF
LEGALLY ACCEPTABLE REP.	Individual authorized by law to consent on behalf of the subject
SUBJECT / TRIAL SUBJECT	Individual participating as recipient of investigational product or control
VULNERABLE SUBJECTS	Those whose consent may be unduly influenced — minors, detainees, employees

Consenting Process — Key Steps

- Give subject adequate time & privacy to review the ICF.
- Encourage questions — discuss all risks, benefits, alternatives.
- Confirm verbal understanding before proceeding.
- Electronic records: audit trail tracks all queries and changes.
- Sign & date ICF in real time — all parties.
- Provide signed copy to subject before any procedures.

Best Practices for ICF Compliance

- Use plain language — consent forms must be clear and jargon-free.
- Include all pertinent study info — risks, benefits, alternatives.
- Voluntary participation — no coercion or undue influence.
- Train all staff on ICH-GCP E6 (R2) consenting procedures.

9 Basic Elements of Informed Consent (45 CFR 46 & 21 CFR 50.25)

- Study involves research — purpose, duration, experimental procedures.
- Risks and discomforts reasonably foreseeable to the subject.
- Benefits to subject or others that may reasonably be expected.
- Alternative procedures or courses of treatment available.
- Confidentiality — extent to which records will be maintained.
- Compensation & treatment if injury occurs (> minimal risk).
- Contact info for questions about research & subject rights.
- Participation is voluntary — withdrawal without penalty.

Frequent FDA Audit Findings

- Incomplete docs — missing signatures, dates, or re-consent.
- Expired/outdated ICF version not approved by IRB.
- Study procedures initiated before signed consent obtained.
- Consent by unauthorized personnel or missing witness sig.
- ICF not in language understood by the participant.