QUICK GUIDANCE

Missing or Incomplete Consent Documentation

What to do when a consent form is absent, unsigned, or uses the wrong version

WHAT IS IT?

Missing Consent Documentation:

The absence of a signed informed consent form (ICF) in the subject's records prior to any study-related procedures.

Incomplete Consent:

A consent form that is unsigned, undated, missing required signatures, or uses an outdated IRB-approved version.

WHEN DOES THIS APPLY?

- A subject's file does not contain a signed ICF prior to study procedures
- A consent form is missing the subject's signature, date, or investigator/coordinator signature
- An outdated version of the ICF was used for consent
- Re-consent was required but not completed
- A monitor or auditor identifies a consent documentation gap

PROCESS AT A GLANCE

1. Identify the Consent Gap

- Review the subject's regulatory file and source records for a fully executed ICF
- Confirm the ICF version used matches the IRB-approved version at the time of consent
- Identify specifically what is missing: subject signature, date, investigator signature, or correct version

2. Notify the PI Immediately

- Inform the PI of the consent documentation issue as soon as it is identified
- Do not attempt to correct the consent form without PI guidance
- Document PI awareness and instructions in the subject file

3. Determine Correctability

- If the subject is available and willing: arrange for proper re-consent using the current IRB-approved ICF
- If a verifiable element is missing (e.g., investigator signature): follow your SOP for late documentation with a clear explanation note
- If an outdated ICF was used: re-consent with the current version and document why the error occurred

4. Document the Issue and Corrective Action

- Create a detailed note-to-file explaining the gap, when it was discovered, and what steps were taken
- Retain all versions of the ICF — including the deficient one — in the subject's file
- Do not discard or alter the original consent form

5. Complete a Reportable New Information report (RNI)

- Initiate an RNI form documenting the consent issue Reportable New Information
- Classify per sponsor and IRB requirements — missing consent prior to procedures is typically a major deviation. A CAPA may be required
- Submit to the IRB and sponsor as required

6. Implement Preventive Actions

- Review consent processes for all active subjects to identify similar gaps
- Implement a consent verification checklist for use at each visit
- Train staff on proper consent documentation requirements

KEEP IN MIND

x Avoid: Do not backdate or forge signatures on consent forms. Do not destroy incomplete consent forms. This constitutes research misconduct and fraud.

✓ **Best practice:** Report the issue to the PI immediately. Document transparently. Work with the IRB and sponsor to address the gap appropriately.

REFERENCES

- ICH E6(R2) Good Clinical Practice Guidelines
- 21 CFR Part 50 — Protection of Human Subjects
- IRB-approved Informed Consent SOP
- Reportable New Information https://research.arizona.edu/sites/default/files/2025-08/Reportable-New-Information-v2025-07.pdf
- Informed Consent V2026-05