



U-MIC TRANSCRIPT

International Council on Harmonisation Good Clinical Practice (ICH-GCP)

Launched in 1990, the International Council on Harmonisation (or ICH) brings together the drug regulatory authorities and the pharmaceutical industry of Europe, Japan, and the United States. Regulatory harmonization offers many benefits to regulatory authorities and the pharmaceutical industry, and ultimately promotes the protection of public health. ICH achieves harmonization through its published guidelines, which are developed through a process of scientific consensus with regulatory and industry experts working side by side. One of ICH's efficacy guidelines—E6, which was introduced in 1996—defines good clinical practice (or GCP) in the conduct of drug clinical trials.

The E6 Guideline was amended in late 2016 with an integrated addendum to encourage improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting. The 2016 amendment—referred to as E6(R2)—also updated standards regarding electronic records and essential documents intended to increase clinical trial quality and efficiency.

Typically, a drug study's sponsor indicates in the protocol whether the study is subject to ICH-GCP guidelines. Keep in mind that reference to good clinical practice without the ICH designation does not indicate that a study must satisfy ICH-specific requirements.

IRBMED offers a checklist for researchers whose work is subject to ICH-GCP standards. IRBMED does not require researchers to submit the completed checklist with their application materials; however, it is a useful tool for guiding them in meeting ICH-GCP E6(R2) standards. Many requirements listed in the document will already be familiar, as they mirror federal and institutional requirements, but some requirements are specific to ICH-GCP. Among the numerous categories addressed in the checklist, ICH-specific requirements relate to

- investigator qualifications and agreement to conduct the clinical trial according to ICH-GCP standards
- adequate resources for conducting the trial
- randomization, blinding, and unblinding, as applicable
- records and reports relating to the clinical trial
- progress reports
- safety reporting
- and final reports to IRB and, where required, other regulatory authorities

Additionally, the checklist addresses numerous consent-related requirements. While many of these overlap with federally required elements of informed consent, ICH-GCP-specific points include

- ensuring that any witnesses to the consent process are impartial
- delineating subjects' responsibilities while participating in the trial
- explaining how subject payment will be prorated, as applicable
- giving each subject a signed and dated copy of the consent document
- and other requirements

ICH-GCP compliance also involves additional scrutiny by the IRB in its review of clinical trials subject to



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ICH-GCP requirements.

Certification Letters, stating that a study has been reviewed in accordance with ICH-GCP guidelines, are provided by IRBMED as necessary for the study team, CRO, sponsor, or other party involved in the research.

Contact the IRB for more information about ICH-GCP requirements and procedures.

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