

Clinical Trial Compliance Key FDA Regulations for Research Organizations

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The intricate web of clinical trial regulations is meant to safeguard study subjects, assure the ethical conduct of research, and ensure the integrity of the scientific results. Any organization that undertakes the responsibility of conducting clinical studies must comply with the rules and regulations set down by three primary authorities: the Food and Drug Administration (FDA), the **Department of Health and Human Services (HHS)**, and **Institutional Review Boards (IRBs)**. Violating their mandates can have serious repercussions, yielding everything from delay to legal action to outright trial rejection.

This article gives an overview of the important regulatory areas that research organizations must be aware of, such as the Food and Drug Administration's 21 Code of Federal Regulations Parts 50 and 56, obligations involving informed consent and institutional review boards, and standards for good clinical practice. It also covers some recent enforcement trends.

Understanding FDA Regulations: 21 CFR Part 50 and 21 CFR Part 56

Core requirements for clinical research, as specified by the FDA, are contained in two major regulations. The first is 21 CFR Part 50, which deals with informed consent. The second is 21 CFR Part 56, which governs Institutional Review Boards.

In order to start, clinical trials must secure informed consent from every participant and obtain IRB approval. The trials themselves, of course, must adhere to GCP to meet basic regulatory expectations, especially from the FDA.

Even with clear regulations, research organizations still encounter frequent issues such as these:

- Informed consent is not properly obtained.
- Oversight by the IRB is neglected.
- Reporting of adverse events or protocol deviations is shoddy.

Informed Consent: A Cornerstone of Ethical Research

It is not only a legal necessity, but also a basic ethical requirement to obtain valid informed consent. It is essential that participants understand exactly what they are getting into when they sign up to be part of a research study. That understanding requires parents when minors are involved, and serious discussions when the potential participants have limited capacities. Even then consent can have a shaky foundation when the study design is complex, or the risk is high.

For informed consent to be legally robust, plain language must be used; participants must be provided with enough time to ask questions; and a written, signed copy of the consent form must be given to the participant. See detailed guidance from the [FDA](#). Related HHS regulations can be found [here](#).

IRB Oversight: Protecting Participants and Upholding Integrity

The critical role of protecting research subjects falls to Institutional Review Boards. IRBs review research protocols and grant the necessary approvals so that work can proceed. They do this, of course, with the intent of limiting and minimizing risks to research subjects. It is the responsibility of these boards, also, to ensure that consent is truly informed and that the subjects understand what they are agreeing to. And finally, these boards have a responsibility to monitor the kinds of events that might be considered adverse.

Researchers must submit detailed protocols, keep accurate records of all IRB communications and approvals, and report any changes or adverse events quickly to steer clear of IRB compliance problems. A handy resource is the FDA's FAQ guide on [IRB regulations](#).

Good Clinical Practice: Building the Foundation for Quality Research

GCP is an internationally accepted standard for the protection of research subjects and the reliability of research data. The principles of GCP underscore the necessity of using qualified investigators, ensuring sponsor accountability, and maintaining accurate and complete records.

You can improve adherence to GCP by conducting internal audits, training all research staff in GCP requirements, and using electronic systems to manage trial data and enable real-time oversight. For a more thorough investigation of the GCP resources available from the FDA, visit [this site](#).

FDA Enforcement: What Happens When Compliance Breaks Down

The Food and Drug Administration takes noncompliance seriously, conducting routine inspections of clinical research sites. Frequent violations that the FDA finds include the following:

- Unreported adverse events
- Missing or incomplete informed consent forms
- Research conducted without IRB approval

The risk of penalties from the FDA can be substantially reduced by organizations that do three things: they train their personnel, they keep records that are adequate to show compliance with the many requirements that apply to them, and they report all unexpected adverse events to the FDA. Here are some things to think about—as well as some real-world examples—when it comes to your organization's training and recordkeeping efforts.

Real FDA enforcement actions serve as powerful motivation.

Ensuring Compliance in Every Trial

Ensuring compliance takes an active, not a passive, approach. It means obtaining IRB approval prior to study launch, gaining informed consent from all participants, and adhering to GCP. It also means keeping good, readable records that allow necessary information to flow easily to the right people. A qualified healthcare attorney can help ensure compliance and prepare you for the inevitable audit or regulatory review.

It's critical to navigate the legal and regulatory landscape of clinical trial research for the success of the trials and the safety of the participants.

Contact us today to make sure your clinical trial is in total compliance with all relevant regulations.