



UNDERSTANDING CLINICAL TRIALS

(What you don't know could hurt you)

A critical part of the medical product-development cycle, clinical trials carry many benefits. They can provide patients with access to the latest drugs and technologies when standard therapies

no longer work. They advance scientific knowledge for researchers. And they help healthcare providers and payors learn what interventions are most likely to be effective at preventing, diagnosing, and treating disease.

The problem? Recent violations of basic ethical standards have eroded public trust and made recruitment difficult. Faced with well-publicized lapses in regulatory oversight, the FDA and other government agencies have redoubled their enforcement efforts. Concerns about financing for-profit manufacturers' cost for R&D have caused both public and private payors to significantly tighten reimbursement policies.

Before you engage in clinical research, you should consider these proactive steps to avoid regulatory, civil, or criminal exposure.

1. Know what the FDA regulates

The Food and Drug Administration (FDA) regulates most human research involving drugs or devices used to prevent, diagnose, treat, mitigate, or cure various diseases and conditions—including products already approved for marketing in the U.S. Not regulated is clinical practice (for example, a physician's decision to prescribe an approved drug "off-label" for clinical use).

2. Identify the sponsor

Clinical trials may be sponsored by a research institution, drug or device company, or healthcare provider. Sponsors have specific responsibilities, including submission of applications and permits, selecting researchers, monitoring investigations, and filing reports to the FDA. Unless you and your staff are trained and able to assume all the attendant responsibilities, you should not become a sponsor. If you're conducting a trial for a manufacturer, be sure the contract clearly identifies that manufacturer as the trial's sponsor.

3. Secure necessary permits

Research involving new drugs and devices often requires an Investigational New Drug (IND) application or Investigational Device Exemption (IDE). Failure to submit the proper application may result in FDA sanctions.

4. Assemble a knowledgeable staff

A well-trained research staff will help ensure regulatory compliance, the smooth handling of applications, and successful recruitment of participants. It's important to clearly notify staff of protocols and expectations, and to document in writing, delegation of any research-related tasks to staff or contracted third parties.

5. Draft clear, consistent documents

Clinical studies may be governed not only by federal and state regulations, but also by multiple documents such as sponsor-investigator agreements, written protocols, and informed-consent forms. All these documents should be clear and consistent, and reviewed by the IRB. To avoid vague or ambiguous language, create a protocol summary that researchers and staff can use as reference.

6. Institute effective billing procedures

Your staff should be fully acquainted with billing and reimbursement practices to ensure compliance with current Medicare, Medicaid, and private payor rules. Be sure to maintain good communications between the research team and sites where participants receive clinical services so as to avoid duplicate billing.

7. Monitor and audit

Most researchers and physicians participate in clinical studies to contribute to scientific progress, help patients, and even benefit from positive PR. But the process is not immune to fraud and abuse. False statements designed to enroll volunteers, payments in exchange for referrals, and fabrication of study data are just a few of the possible abuses, and sponsors and investigators may be held responsible even if they take swift and appropriate corrective action. If you suspect a problem in the conduct or oversight of a study, consult experienced legal counsel for assistance.