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Drug and Device Trials: Opportunities, Challenges, and Practical Solutions

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Clinical trials are an essential part of medical product development. They serve to identify the most promising interventions for preventing, diagnosing and treating disease. In many cases, they allow patients to access the latest technologies when "standard" or "proven" therapies have failed or are unlikely to work. For researchers, they help advance scientific knowledge and understanding. And for healthcare providers, they can also furnish a supplementary source of reliable income.

Yet today, the research community faces tremendous challenges. Rare but serious violations of basic ethical standards have eroded public trust and made recruitment difficult. The FDA and other government agencies, faced with well-publicized lapses in regulatory oversight, have redoubled their enforcement efforts. And payors, concerned about underwriting for-profit manufacturers' research and development costs, have significantly tightened reimbursement policies.

Those performing clinical research should consider these proactive steps to reduce legal exposure:

Know Which Projects are Regulated

The FDA regulates most drug and device studies. The agency does not, however, regulate clinical practice, like a physician's decision to prescribe an approved drug "off-label" to an individual patient.

Identify and Secure Necessary Permits

Research involving novel drugs and devices typically requires an "investigational new drug" application or "investigational device exemption" to proceed. Studies involving approved drugs or devices used off-label are sometimes, but not always, exempt from these requirements.

Assemble a Well-Trained Staff

Experienced staff can help assure regulatory compliance and smooth operation of a study. They can expedite IRB handling of applications, efficiently secure necessary approvals, and compile other required data and documentation. Sponsors are more likely to work with and support sites that can reliably recruit research participants and conduct their studies consistent with applicable regulations and contractual obligations. Poorly trained staff, by contrast, can trigger inadvertent non-compliance, risk regulatory sanctions and, most important, threaten the safety of research participants.

Draft Clear and Consistent Study Documents

A study may be governed not only by federal and state regulations, but also by research agreements, written protocols, investigator's brochures, informed consent forms, and other documents. Make sure all are consistent. Clarify any vague or ambiguous provisions before beginning enrollment. Consider developing a protocol summary that researchers can consult to avoid unauthorized deviations.

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Clearly Identify the Sponsor

A sponsor may be a drug or device company, a research institution, or an individual health care provider. The sponsor has significant responsibilities, including submission of applications or permits to conduct the research, monitoring the investigation, and filing FDA-mandated reports. Research agreements should clearly specify who is the sponsor. If the sponsor delegates any of its obligations, these should be clearly spelled out to assure that the other party is accountable to the sponsor and to FDA for appropriately executing them.

Institute Effective Billing Practices

Effective communication between the research team and study sites is essential. This can help avoid double-billing the research sponsor, the study participant, and/or the participant's insurance carrier. Assure that billing staff are familiar and comply with current Medicare, Medicaid, and private payor rules on billing and payment for trial-related services.

Integrate Research into Your Audit and Compliance Program

Most of those who conduct clinical trials want to contribute to scientific progress, gain access to the latest developments for their patients, and, perhaps, benefit from the attendant positive publicity. But research is not immune to fraud, waste, and abuse. Examples of problematic activities include false statements to induce participation; payments in exchange for referrals; enrollment of ineligible participants; and fabrication or falsification of study data or results. If problems are identified in the conduct or oversight of a study, consult promptly with experienced legal counsel for assistance.

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