What Should Be on Your Clinical Trial Investigator Site Audit Checklist?

What Should Be on Your Clinical Trial Investigator Site Audit Checklist?: You live and operate in a regulated industry. Obviously, it’s crucial that you stay in compliance during your clinical trials. That’s because failure to do so has enormous and expensive consequences. And yet, on a regular basis, firms find themselves with an FDA 483 for non-compliant behaviors. To prevent this, we recommend firms conduct audits to ensure compliance with FDA regulations.

So what should be on your audit checklist to ensure FDA compliance during clinical trials? Check out our comprehensive checklist of things to examine during your own mock audit, along with tips and advice from our experts.

**Clinical Trial Audit Checklist**

Firms should conduct their own mock audits on a regular basis to ensure compliance and identify areas for improvement. Each checklist section described below is a very brief summary of the compliance area. However, it is important to keep in mind that this checklist is not meant to be inclusive of all items that should be examined during an audit.

**Protocol Compliance**

This ensures that documentation is available to substantiate that the clinical Investigator and the site staff have followed the study protocol approved by the Institutional Review Board (IRB).

**Institutional Review Board**

Documentation of IRB approval of the protocol and any amendments, informed consent documents, advertisements, and other information provided to prospective study subjects must be kept onsite.

**Human Subject Records**
This is one of the most significant areas of the site audit. Here, the auditor is looking through the study documents and records to make sure that all of the required information is captured and follows the protocol without deviations. Documents reviewed include informed consent forms, medical records, and other source documents.

**Other Study Records**

Other records pertinent to the study may include administrative study files, correspondence files, master subject list, appointment books, sign-in logs, screening lists, and MedWatch forms.

**Informed Consent of Trial Subjects**

Ensuring that each subject, or the subject’s legally acceptable representative, has given uncoerced informed consent is essential in every trial. Written IRB-approved informed consent forms, along with any other oral or written information, must be as non-technical as possible and must be understandable to the subject. The written consent form must be revised when new information becomes available that may be relevant to the subject’s willingness to continue participation in the research, and the communication of this information should be documented.

**Financial Disclosure**

All investigators and relevant study staff must sign a document disclosing information about their financial interests to the sponsor. This document must be updated if circumstances change.

**Electronic Records and Electronic Signatures**

If electronic records are being used as detailed in the study protocol, the system used to generate, collect, or analyze the data must be documented and meet the requirements applicable to paper records. Training must also be provided to the appropriate personnel.

**Test Article Control**

Drug accountability at the Investigator site must be verified. The drug must be received by authorized personnel, properly labeled, inventoried, secured, and stored under the appropriate conditions. The return of any quantities of the drug to the sponsor, or otherwise disposed of, must also be documented.

**Record Custody and Retention**

Study records must be stored and retained according to the protocol and regulations.

**Reports to Sponsor**

Investigators always need to keep the Sponsor apprised if there are any safety issues or protocol deviations, as such, this section is used to determine whether required reports
have been submitted to the Sponsor in accordance with the study protocol and regulations.

**Investigator qualifications and Agreements**

Auditors determine whether the Investigator has adequate experience in conducting trials; to ensure that they and their staff have been adequately trained, and that they are knowledgeable of GCP and the applicable regulatory requirements.

**Adequate Resources**

The Investigator must have sufficient time to conduct and complete the trial safely and adequately. The Investigator shall have an adequate number of qualified staff, and adequate facilities for the foreseen duration of the trial.

**Medical Care of Trial Subjects**

The Investigator is responsible for the wellbeing of the subjects including oversight of all trial-related decisions and ensuring that adequate medical care is provided to subjects including medical care for any adverse events related to the trial.

**Communication with the IRB**

Audits shall include verification that the Investigator has written and dated approval from the IRB regarding the research application, written informed consent form, consent form updates, subject recruitment, and any other written information to be provided to subjects.

**Randomization Procedures and Unblinding**

The Investigator is expected to follow the trial’s randomization procedures. Additionally, if the research is blinded, the Investigator must comply with the protocol requirements to maintain the blind and to promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product.

**Records and Reports**

The Investigator must ensure that all data reported to the sponsor is accurate, complete, legible, and timely. If there is a change or correction, it must be dated, initialed, and explained without obscuring the initial entry. This applies to both written and electronic changes or corrections.

**Progress Reports**

The Investigator will submit written summaries of the research status to the IRB annually, or more frequently if requested by the IRB. The Investigator must also immediately report all serious adverse events to the sponsor.
Regulatory Essentials

Auditors shall ensure that the regulatory binder contains all of the required documentation which should include, at minimum, Form FDA 1572, protocol, informed consent, Investigator’s brochure, advertisements, enrollment log, and all IRB-approved letters.

Study Staff

Auditors shall review all staff CVs and licenses to ensure that they are appropriately qualified for their delegated roles and have all been properly trained.

Data and Safety Monitoring

High-risk trials may have a data safety monitoring board (DSMB). Safety monitoring reports are reviewed to ensure there are no significant noncompliance issues or any patterns of ongoing or unresolved compliance.

Record Archiving

Reports, essential documents, and data has been neatly organized and kept in an appropriate and secure place.

Premature Termination or Suspension of a Trial

If the trial is prematurely terminated or suspended for any reason, the Investigator must promptly inform the trial subjects, assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), inform the regulatory authority(ies).

Final Report by Investigator

Upon completion of the research, the Investigator must inform the IRB and provide a summary of the research results as well as any reports required by the regulatory authority(ies).

Why Should You Conduct an Independent Audit?

Conducting your own audit is a good start, but we recommend firms also get a third-party to perform an independent audit to ensure things don’t slip through the cracks.

Independent audits are specifically designed to give you a fresh and unbiased look into the quality systems associated with your program. Most importantly, it is the objectivity inherent in an independent audit that establishes the ultimate value. Obviously, if a party associated with the program conducts the audit, that party may overlook or even downplay important issues because it may be in their interest to do so.

For instance, many contract research organizations (CROs) also conduct audits. While it may be convenient for the sponsor to have the CRO conduct an audit as a part of its
services, it is not a good idea because the CRO would be auditing themselves. The CRO has an interest in the outcome of the audit and, therefore, cannot be completely objective.

One of the major reasons why firms conduct audits is to uncover issues and fix them before the FDA finds them, and independent audits are crucial because they give you an unbiased look at your processes. Proactively analyzing your processes identifies potential issues before they become larger problems, which also helps keep the product’s development on track.

How Independent Audits Ensure Vendor Compliance

As you know, your entire drug development program can cost tens of millions of dollars while taking place over several years. That’s a huge investment in money and time. As such, if one of your clinical or manufacturing vendors gets something wrong and you don’t know about the mistake until it is uncovered by the FDA, it becomes a huge and costly problem.

Having the FDA discover gaps in any one of your vendor’s quality systems is exactly what you don’t want to happen. That’s because when this happens, the FDA can order remedial actions or invalidate the entire trial. This means, at the very least, you will need to spend money that you haven’t budgeted to take corrective actions. In the worst-case scenario, you risk losing your entire investment.

Independent audits help prevent this because the third-party also examines the processes of your contract vendors to ensure compliance throughout your supply chain. By identifying problems before the FDA does, you are taking important steps towards staying in compliance and protecting your drug development program.

Protect Your Drug Development Program with Our Help

Use our audit checklist as a starting point, but ensure FDA compliance during clinical trials and drug development by letting the ProPharma Group conduct an independent audit of your processes and partners.

Experienced professionals conduct our independent audits with the highest levels of accuracy and consistency. Further, we work with our clients to help develop quality systems and metrics that track on-going compliance activities. This means you can count on us to help safeguard your investment by closely examining your business in addition to determining whether your clinical and manufacturing contract vendors are maintaining optimum quality systems.

Contact us today to learn more about our independent audit services.

Stay in Compliance with Our Help

Let us help you stay in compliance with FDA regulations during your clinical trial.
ProPharma Group’s audits are conducted by experienced professionals worldwide who produce audit reports with the highest levels of accuracy and consistency. Further, we work with our clients to help develop quality systems and metrics that track on-going compliance activities. To learn more about our independent audit services, contact us today.