

# Investigator Responsibilities for Clinical Research Studies: Proper Staffing Can Ensure an Investigator Is Compliant

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**T**he Code of Federal Regulations states that a clinical research investigator is responsible for conducting clinical research in compliance with the signed agreement, investigational plan, and U.S. Food and Drug Administration regulations. In order to meet all the research requirements, the proper research staff is critical. A dedicated, experienced clinical research coordinator is key. The research coordinator represents the investigator when interfacing with the corporate sponsor of the study and the practice staff to ensure that subjects are qualified and that the protocol is followed. Due to the wide range of responsibilities that a clinical research coordinator has, there are three skills that a quality research coordinator must possess: attention to detail, organizational and process understanding, and confidence.

**Key words:** Clinical research investigator; clinical research coordinator; study investigator responsibilities; clinical research staffing.

Before a new medical treatment can be released to the U.S. market, the manufacturer has to prove to the U.S. Food and Drug Administration (FDA) that the new treatment is safe and effective. Human testing is the most reliable way to determine if a new device or drug is safe and effective in humans. Collecting human data on the safety and effectiveness of a device and/or drug is accomplished through a clinical research study and is regulated by the FDA.

A successfully executed clinical research study requires an equivalent or superior new device or drug, a scientifically sound investigational plan, and competent clinical research personnel at the corporate level and at the clinical research site. After spending millions of dollars on developing a new technology or drug, companies depend on the clinical research study investigators that they have vetted, selected, and trained to conduct an ethical and compliant study at the investigators' site.

## INVESTIGATOR RESPONSIBILITIES

An investigator may not have editorial rights when it comes to the investigational plan or the development of the device, but by law the investigator is wholly responsible for conducting an ethical and compliant clinical research study at his or her site.

The Code of Federal Regulations states that an investigator is responsible for ensuring that a study is conducted according to the signed agreement, the investigational plan, and applicable FDA regulations; protecting the rights, safety, and welfare of subjects under the investigator's care; and controlling the devices under investigation (per 21 CFR Ch. 1 § 812.100).

The Code of Federal Regulations is clear; it is the investigator that must ensure that he or she is conducting the study in compliance with the signed agreement, the investigational plan, and all applicable FDA regulations.

The sponsor, a company that is funding the research, is responsible for ensuring that the investigators are qual-

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ified to participate in the study based on their training and experience. It is also the sponsor's responsibility to monitor the data at the investigator's site for accuracy and compliance. The sponsor may assist the site by supplying guidance, tools, and written instructions, but it remains the investigator's responsibility to conduct a clinical research study in compliance with the regulations.

The consequences for not adhering to the regulations range from minimal, such as a couple of hundred hours dedicated to corresponding with the sponsor, the FDA, and the institutional review board (IRB) discussing issues that have arisen at the study site and ensuring that the investigator is aware of the magnitude of those issues; completion of additional training for the investigator(s) and the research staff; data auditing by the sponsor and the FDA; and/or developing new corrective action plans and standard operating procedures to ensure that similar issues will be managed properly. The maximum consequence for not adhering to the regulations would be the investigator losing his or her medical license and/or serving a prison sentence (for ethics violation or fraud).

An investigator can be in noncompliance relatively quickly; and while the investigator may believe that it is by no real fault of his or her own, the person held responsible for noncompliance at a site is the investigator.

The consequences of a poorly run study can be dire, but the rewards of a scientifically executed study may include becoming a key opinion leader, which leads to more podium time and publications, greater research opportunities, more access to new technology for your patients, and expansion of your medical practice. In the age of the consumer-patient, patients search for physicians that are actively learning and expanding their skills. Participation in clinical research is a sign to patients that a physician and practice are interested in current treatments.

Investigators are compensated by the study sponsor for their time, expertise, and a portion of their overhead costs associated with conducting a clinical research study. The fees paid by the study sponsor are negotiable. Study sponsors are aware of the extra time and dedication it takes for the physician and the practice's clinical research staff to ensure that qualified patients consent and are enrolled properly into a study, that all tests and case report forms are completed per the protocol at each follow-up visit, that patients return at the proper times, and that all reports to the sponsor, IRB, and FDA are completed on time in order to maintain their site's approval to conduct the study.

## THE ROLE OF A CLINICAL RESEARCH COORDINATOR

If an investigator's goal is to maintain a compliant study, then it is imperative to have a competent, experi-

enced, trustworthy staff dedicated to clinical research. Proper staffing is dependent upon the number of studies in which an investigator and/or practice is participating. To have a proper research staff as a single-study investigator, a seasoned clinical research coordinator will suffice. This may even be a part-time clinical research coordinator, but it is recommended that a dedicated researcher be hired.

If it is the goal of the investigator and the practice to be a research center, then it is imperative to have a full research staff, which may consist of the following personnel: clinical research medical director, regulatory coordinator, and clinical research coordinators.

Proper staffing is the key to an investigator's research reputation. The critical member to the research team is the clinical research coordinator. If an investigator wants to be taken seriously and thought of as a must-have investigator by a study sponsor, then a dedicated clinical research coordinator must be appointed. This is an investment for the future. Investigators and other medical practice staff are too busy to maintain patient and regulatory binders, track patient visit windows, report adverse events to the study sponsor and IRB in a timely manner, and comply with the idiosyncrasies of each protocol and the required paperwork.

### ***A clinical research coordinator is the cornerstone to an investigator's clinical research.***

In an effort to reduce expenses and increase profitability, an investigator may think it is good practice to double-task a salaried employee by increasing the responsibilities of the employee to include the daily tasks of a clinical research coordinator. Physician assistants, nurse practitioners, medical assistants, office/practice managers, interns, and personal assistants have all been tasked with the responsibility of study site research coordinator in addition to their current full-time job. This is not a good idea. The employee becomes overworked and often overwhelmed by having to complete his or her original daily tasks, learn new terminology and study requirements, and be the point of contact for a demanding sponsor that has millions of dollars invested in a new device.

A clinical research coordinator is the cornerstone to an investigator's clinical research. A skilled and competent coordinator makes a clinical research subject feel comfortable, keeps the sponsor informed about study progress, and ensures that the investigator is following the protocol.

The responsibilities of a clinical research coordinator may include but are not limited to:

- Track investigator agreement;
- Schedule and participate in study-specific training;
- Submit study to IRB for approval;

- Screen and review potential patients' charts;
- Explain clinical research to potential research subjects;
- Answer questions about the study;
- Work with insurance companies regarding reimbursement;
- Randomize subjects;
- Complete and submit data to study sponsor;
- Schedule patients for follow-up visits;
- Address data discrepancies; and
- Provide study updates to study investigator.

## CLINICAL RESEARCH COORDINATOR ATTRIBUTES

A medical background need not be a requirement for a clinical research coordinator. There are three soft skills that are more important than having a medical background: attention to detail, organizational skills, and confidence.

### Attention to Detail

It seems obvious that a position that requires data collection for research purposes or analysis demands a person that is detail-oriented. An investigator relies on a clinical research coordinator's ability to be detail-oriented. All protocol deviations are reported to all active research sites and the FDA for review. Minimizing deviations is important to the integrity of data.

A common protocol deviation that can be easily avoided is a study subject signing an expired version of an informed consent form. The approved consent looks exactly like the expired consent, except for the date stamped on the front of the form. This deviation makes it appear as if no one at the site is paying attention to the details, which encourages auditors, corporate and FDA, to dig deeper searching for other mistakes.

A candidate interviewing for a research coordinator position understands that attention to detail is a skill that is required for the position. It is difficult to determine if a person is detail-oriented during the short time allotted for an interview, but there are signs that the candidate does not have an eye for details—review the candidate's resume for misspelling, incorrect usage of words, and formatting discrepancies.

### Organizational Skills

Organizational skills are essential. An investigator needs a coordinator that can create systems to automate study actions. Systems and processes lead to fewer protocol deviations, data deficiencies, and missed visits. Systems can also be directly linked to higher enrollment rates. A person that can make the prescreening process more efficient through prescreening checklists may increase the enrollment rate by not overlooking a potential patient. A higher enrollment rate of qualified patients increases an

investigator's chance to be the lead author on peer-reviewed journal articles.

### *The study coordinator is the face of the practice to the sponsor.*

When an organizationally driven research coordinator is interviewed, he or she will speak of systems and processes that can be implemented to identify a patient as a potential research subject and proactively notify the coordinator and investigator if a patient should be included in a study. Good systems include color-coding study patients' charts, pop-ups for electronic data systems that notify the practice staff that particular patients are research study subjects, and regular training programs for the schedulers, x-ray technicians, billers/coders, and other practice staff that come in contact with study subjects or their medical or study record.

### Confidence

Lack of confidence should be considered a deal breaker for the position of clinical research coordinator. The coordinator is the face of the practice to the sponsor. He or she will have weekly contact with the study sponsor addressing enrollment, data, and reports. The coordinator works with the study monitor during an audit to address issues or discrepancies with the study patients and data. The coordinator has to be willing to disagree with a study monitor if the coordinator believes the monitor is not accurately interpreting the protocol instructions, and has to be able to explain why a particular action was taken.

Confidence is also important because the coordinator is the person that an investigator relies on for direction. There may be times when the coordinator has to tell an investigator that he or she is not right. Together, the investigator and coordinator work to submit clean, ethical data on qualified patients according to the investigational plan and instructions.

## CONCLUSION

The regulations clearly state that it is the investigator's responsibility to conduct a clinical study properly. This is accomplished with the proper staffing. The proper clinical research staff must include a carefully selected clinical research coordinator that shows attention to detail, understands and implements systems and processes, and is confident when speaking with study sponsor personnel and medical practice investigators. The proper staffing of a clinical research study is the responsibility of the investigator. The time spent determining if a candidate fits the role of clinical research coordinator equates to time and money saved in the long run. ■