

the CRA more clout at the site. No matter how involved the CRA is, he or she should have a good understanding of both the process and the specifics for a site, in order to be able to discuss the grant with the investigator and answer any site questions.

## **Contracts**

A contract between the sponsor and the investigator will be signed before the trial starts at a site. This document usually contains the responsibilities of the investigator, including the number of subjects the site is expecting to enroll, timelines for enrollment, grant amounts and the regulatory requirements for the investigator. It also contains the responsibilities of the sponsor, including when and how grants will be paid, monitoring of the study and sponsor regulatory requirements. It will be signed by the appropriate company representative, and by the investigator. [Note that in large institutions contracts may be signed by someone in the contract office rather than by the investigator.]

Contracts are rarely written, negotiated or signed by the CRA. The CRA may, however, be asked to take the contract to the investigator and/or collect the signed contract. The CRA will want to have a copy of the contract, if possible, to know what was agreed to for enrollment, timelines and payment schedules.

## **Key Takeaways**

### **Study Documents**

- There are a number of documents that are required before a study can begin at a site.
- Most sponsors will not ship the study drug until all required documents are collected.
- Copies of all documents must be kept in both the site's and the sponsor's study files.
- The CRA should keep track of the IRB approval process and letter, so the study is not unduly delayed.

### **Financial Disclosure**

- The purpose of financial disclosure is to identify any potential conflict of interest that could bias a clinical trial.
- Financial disclosure information must be gathered for all people listed on the 1572, and their immediate family members.
- These data are collected for the time period of the study and one year following.
- Financial disclosure information is reported to the FDA when the NDA is filed.

### **Investigator Meetings**

- All investigators and coordinators, as well as relevant sponsor personnel, should attend the meeting.
- The meeting should be held at the time when most sites are ready to enroll.
- The purpose of an investigator meeting is to ensure that all sites have the same understanding of all protocol and administrative procedures.
- Sponsors should always have a full rehearsal before the meeting.
- CRAs should act as the host for their respective sites and ensure that site personnel meet the sponsor representatives.

### **Study Initiation Visit**

- The purpose of an initiation meeting is to ensure that everyone at the site has a clear and accurate understanding of how the study is to be done.
- This meeting should be held after a site has all the study supplies, including the study drug, but before study personnel enroll any subjects.
- All relevant site personnel should be present for the meeting.
- The CRA is in charge of the meeting.
- The meeting should be documented in both the investigator's and sponsor's study files.

### **Investigator's Study Files**

- Investigators are required to keep study records and documents both during the trial and after the trial is closed.
- CRAs can help the investigator set up and organize these files and must check them regularly throughout the study.
- Maintaining files appropriately will ensure that they are in order for an audit.
- It is often simple to catch and correct problems with the files on an ongoing basis throughout the study. It may be impossible to correct the files when the study is over.

### **Grants and Contracts**

- A CRA should be knowledgeable about grants and how they are calculated.
- If involved in payments, the CRA must track the study progress to keep abreast of money owed.
- Most grants are prorated by visit for each subject.
- Contracts between the sponsor and the investigator are signed before the study starts at the site.

### **References**

1. Guidance, Financial Disclosure by Clinical Investigators  
[www.fda.gov/oc/guidance/financialdis.html](http://www.fda.gov/oc/guidance/financialdis.html).
2. 21CFR312.53 and 21CFR812.43 (devices).