

## [Sponsor](#)

### **Sponsor**

#### **Requirements**

Copy of all significant correspondence to and from the study sponsor(s) (e.g., letters, e-mails, meeting notes, and notes of telephone calls)

#### **Tips / Additional Information**

If documents are filed electronically, write a signed and dated note to file indicating the location.

#### **Signed Agreements**

- Copy of all signed agreements, including financial agreements, between involved parties, including:
- Investigator/institution and sponsor
- Investigator/institution and Contract Research Organization (CRO)
- Investigator/institution and other authorities

#### **FAQs**

Q: Some of our e-mails and phone calls with the study sponsor concern minor issues or clarifications. Is it really necessary to document and save all such communication with the study sponsor(s) when we are already so pressed for time?

A: Yes. A complete record of correspondence contributes to a well-documented audit trail. What seems minor now may assume much greater importance in the future if a problem arises. It also helps the investigator to track all decisions and changes that may be important to confirm later. As always, all notes should be signed and dated.

Q: What should I do if the Principal Investigator (PI) keeps a copy of all agreements in a locked file in their office?

A: Include a signed and dated note-to-file indicating the location of these documents.

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Applicable GCP sections:

- [8.3.11](#)
- [8.2.5](#)

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