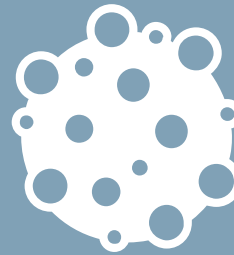




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Inspection Interview

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PPD[®]

Inspection Interview workshop summary

- Information provided to the inspector(s) were not accurate, complete, and relevant for the inspected study.
- The interviewee did answer questions outside of his/her job responsibilities or experience
- Volunteering of information
- Providing documents which were not requested
- Guessing information, speculating
- Arguing with inspector, expressing disagreement not holding good arguments



Inspection Interview workshop summary

- 👉 Investigator of Record was not able to demonstrate his/her oversight
- 👉 Blaming Sponsor/CRO for not providing adequate instruction
- 👉 Making inappropriate comments about the systems used for the study
- 👉 Asking inspector for advice
- 👉 Inappropriate use of Notes to File



Inspection Do's & Don'ts

- Refresh your knowledge on your study tasks, study protocol and any applicable guidelines, relevant procedures, as well as on local regulations relevant for your work.
- The Investigator of Record is ultimately responsible for all study-related activities at his/her site, regardless of who has been delegated the various study responsibilities and must be able to demonstrate this during interview

Am I Prepared for Interview?



Inspection Do's & Don'ts

- Answer the question fully but don't volunteer more information about other topics
- Communicate, make things clear
- Be positive and confident
- Make sure you completely understand the question before you answer
- Only answer questions that relate to your function and questions which you can fully answer



Inspection **Do's** & **Don'ts**

- 👉 **Never** say never
- 👉 Do not **argue**
- 👉 Do not **guess, lie** or **speculate**
- 👉 **Blame** others
- 👉 **Deny** the obvious
- 👉 Make **false/misleading** statements
- 👉 Become **upset**
- 👉 **Volunteer** information
- 👉 Supply **personal or financial** information.



Inspection **Do's** & **Don'ts**

- 👉 **Don't respond** to questions **outside your area** of expertise.
- 👉 Don't be embarrassed to **say you don't know** the answer to a question but indicate that you'll find out.
- 👉 Don't bring **any extra documents** to the inspection room that have not been requested.



Inspection Do's & Don'ts

- 👉 Note to File (NtF) is not a panacea for all things that have gone wrong
- 👉 Documenting a mistake means absolutely nothing during an inspection
- 👉 The NtF are a road map for any inspector and air all of the site's faults
- 👉 When used properly Note to File can be a positive practice. A useful NtF has the following parts: a problem is identified, the root cause is identified, appropriate corrective and preventative actions are implemented for preventing reoccurrence

Inspection Do's & Don'ts

Failure to secure investigator compliance with the investigational plan and applicable FDA regulations [21 CFR 312.56(b)].

Our investigation found that Sponsor failed to take any action to secure compliance while the study was ongoing except to generate numerous memos to the file after all subjects had completed the study.

According to an FDA interview these memos to file served as a mechanism to train the investigator. We note that generation of numerous memos to file after all subjects have completed the study does not adequately secure Compliance of an investigator.



Inspection Do's & Don'ts

At least 89 memos to file were generated during the monitoring visit to address these violations. As noted above, generation of memos to file after all subject shave completed the study does not adequately secure compliance of an investigator.

