FDA Inspections

• Inspections occur:
  • Routinely – e.g. an NDA is submitted and FDA is required to review the data
  • “For Cause” – e.g. a complaint regarding research conduct is received by FDA
Inspection Goal

• To assist the Inspector with the review to achieve a successful outcome
  • Patient safety is a priority of the research team
  • Demonstration of a cohesive research structure
  • Commitment to Research Integrity and Transparency
Interaction Guidelines

• Be professional
  • When the inspector arrives, asks to see their credentials
• Answer questions honestly and factually and to the best of your knowledge
  • Avoid guessing at an answer – it’s ok to say you don’t know something.
  • Do not offer unsolicited comments – do not go beyond the scope of the question
    If the question is a “yes” or “no” question; do not provide additional information unless requested
• Do not offer personal views or comments
• Avoid generalities: words such as “generally,” “typically,” “usually” invite additional questions
• Do not speculate about an answer: offer to find a subject matter expert (SME)
Interaction Guidelines

• Be comfortable with silence
• Do not argue
• Do not place blame
• Do not refuse to provide requested information
• Don’t be defensive or appear to be concealing information
• Don’t imply deficiencies are due to lack of resources
Interaction Guidelines

• Only provide what is asked for
  • If asked to provide subject binders: ask which subject numbers the Inspector would like to see
  • If asked to provide the DOA; only provide that file

• Do not “instruct” colleagues on answers – each individual may have a different perception on events that happened.
Interaction Guidelines

• Make sure cell phones and pagers are on VIBRATE when you are in the room with the Inspector!!

• Escort Inspector when leaving the designated review area
Typical Agenda

• Opening Meeting
  • PI receives form 482 – Notice of Inspection
  • Introductions are made (have business cards available for Inspector if possible)
    • Principal Investigator
    • Representatives of the Institution (e.g. OVCR; IRB; OCT)
    • Key members of the study team (can also have sub-investigators available)
  • Review of General Information related to the Inspection
  • Inspector may have some general questions related to the conduct of the study
    • “How many studies does the PI currently have?” – includes enrolling/follow up
    • “How many subjects were recruited into those studies
    • “How were subjects recruited into this study/How many dropped out?”
Typical Agenda

• Daily Meeting(s)
  • Discussion of open items from previous day/next steps – PI should be available if possible (in-person or via telephone)
  • Review continues
  • End of day Wrap-Up meeting
    • Summarize any open items to be followed up and be prepared to provide answers the following day
    • Ask questions of the Inspector – is there anything the PI or study team might be able to clarify at this time to avoid a 483
  • Make sure any copies that are requested by the Inspector are duplicated for the study team’s files
Typical Agenda

• Wrap Up Meeting
  • Inspector reviews any observations made regarding the inspection
  • This is the time a form 483 would be issued (Inspectional Observations)

• Use this time to talk with the Inspector to clarify any of the observations made
  • Clarifications will help with the response to the FDA
After the Inspection

• Schedule a Debriefing meeting with:
  • Key study members
  • Office of the Vice Chancellor for Research
  • Office of University Council
  • Office of Clinical Trials

• If a 483 was issued: (First rule is: Don’t Panic!! - Second rule is: Don’t Panic!!)
  • 15 Business Days to Respond
  • Support Available from OVCR/OUC/OCT to help prepare the response
    • The response will come from the PI AND the OVCR
Questions?

If you have any questions prior to, during, or at the end of the inspection, please contact the Office of Clinical Trials – Clinical Trial Quality Assurance Program.

919-843-2698

or

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We are here to support you!