Before the Site Inspection

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- Complete the FDA Site Pre-Inspection Checklist and identify records the FDA is likely to audit.
- Identify all subjects
- Locate and print copies of the study enrollment/screening log
- Locate and have readily accessible ALL Informed Consents
- Locate and have readily accessible ALL Case Report Forms and all supportive source documentation
- Sequester these records and any reviews or prep work done in anticipation of the visit for easy access, but do not volunteer any of these records to the inspector unless directly asked. Always wait for a specific request to provide information.
- Expect to have an initial meeting with the inspector in a private room prior to the start of the inspection.
- Secure a private for the initial and exit meetings and a room for the inspection Depending on the space the initial and exit meetings can be conducted in the same space as the inspection.
- Upon notification of the inspection, the coordinator should review the Coordinator Checklist.

Inspector Arrival

Please also refer to your department policy for FDA site inspections.

- There may be times when persons outside the study team (e.g., department directors) should be notified that the FDA is conducting an inspection in the building.
- If the location where the initial meeting and inspection will occur require the use of a sign in log, and the inspector will not sign in, make a note in the sign in log of the name, date/time, purpose and escort name.
- The escort should walk the inspector to an appropriate meeting room. The inspector will present his/her credentials to verify that they are in order; do not expect the investigator to permit a copy to be made of the badge/credentials.
- The inspector will then present a Notice of Inspection (Form 482) to the Principal Investigator. This notice authorizes the inspection and its presentation officially begins the inspection.
- The inspector will explain the intended purpose and scope of the inspection, and then ask the PI to summarize the study.The PI should expect inquiries in any of the following areas during this initial meeting:
    - Experience as a Clinical Researcher
    - Oversight of the study
    - Oversight of the investigational product
    - Oversight of study personnel

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