

# FDA Site Inspection Guide

## Appendix 1

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### Initial Intake Form

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**Take good notes during all communication and interaction with the inspector.**

#### Initial Contact Information

Staff member who received FDA communication:

Contact/Notification Date:

Anticipated Start Date:

Expected Duration:

#### Inspector Contact Information

Name:

Title:

Telephone:

E-mail:

Additional inspector names:

#### Purpose of Inspection – Who and what are being inspected?

*Wait for specific answers. Do not make suggestions.*

☐ Clinical trial(s)/study:

☐ Principal Investigator:

☐ Co-Investigator(s):

☐ Routine (i.e. IND)

☐ Directed (for cause)

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☐ Follow-up (i.e. 483; warning letter)

☐ Other

### Additional Details:

Has the FDA requested that specific personnel be available? ☐ Yes ☐ No

Name	Date

Has the FDA requested that specific documents be available? (List on separate sheet if needed)

Request that the inspector provide in writing the exact documents that s/he wishes to review. S/he may not provide this, but you can request it.