

**UPCOMING FDA OR OHRP INSPECTION**

**Basic information:**

|  |  |  |
| --- | --- | --- |
| Call date: | |  |
| Starting date: | | Expected Duration: |
| FDA  Inspector Information | Name | |
| Telephone | |
| Title | |
| Additional FDA Investigators’ Names? |  | |

**ask for the following information:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Who / what is being inspected? *Wait for specific answers. Do not make suggestions*. | | | | |
|  | Clinical trial(s)/study |  | | |
|  | Principal Investigator  Co-Investigator(s) |  | | |
|  | Other |  | | |
| Why is the inspection being done? *Wait for the answer. Do not make suggestions*. | | | | |
|  | Routine? (i.e. IND) |  | | |
|  | Directed (for cause)? |  | | |
|  | Follow-up (i.e. 483; warning letter ?) |  | | |
|  | Other |  | | |
| Does the FDA want specific personnel available? No / Yes →if yes, then list | | | | |
| Who | | | | When |
|  | | | |  |
|  | | | |  |
| Does the FDA want specific documents available? (List on separate sheet if needed) | | | | |
| Does the FDA want any of these documents sent prior to their arrival? No / Yes →then list: | | | | |
| Documents: | | |  | |
|  | | |  | |
| Address: | | | How? Overnight Registered Certified | |
| Delivery by when? | |

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