

**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 InvestigatorCo-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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