This document has been created by the UW-Madison FDA Regulated Research Oversight Program as guidance to help investigators and research staff throughout the process of a Food and Drug Administration (FDA) inspection.

**It is important to take detailed notes during all communication and interaction with the inspector/auditor.**

**Communication**

When you are contacted to schedule a site visit, obtain the following information:

Date of Call: Anticipated Start Date: Expected Duration: days

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| --- |
| **Auditor/Inspector Contact Information:** |
| Name:  |
| Telephone:  |
| Title:  |
| Additional Auditor/Inspector Names: |

|  |
| --- |
| **Ask the following questions:** |
| Who / what is being inspected? *Wait for specific answers. Do not make suggestions*.  |
| [ ]  Clinical trial(s): |  |
| [ ]  PI, Co-I(s): |  |
| [ ]  Other: |  |
| Why is the inspection being done? *Wait for the answer. Do not make suggestions*.  |
| [ ]  Pre-approval? (i.e. NDA/ANDA)[ ]  Routine? (i.e. IND, manufacturer)[ ]  Directed (for cause)?[ ]  Follow-up (i.e. 483; warning letter?)[ ]  Other | Details:  |
| Does the auditor/inspector want specific personnel available? [ ]  Yes [ ]  No → ***If yes, list below*** |
| Who  | When |
|  |  |
|  |  |
|  |  |
|  |  |
| Does the auditor/inspector want specific documents available? [ ]  Yes [ ]  No * ***If yes, list below and on a separate sheet, if needed.***
* ***Ask the auditor/inspector if he/she would like to review any specific documents but do not volunteer additional information or documentation.***
* ***If the inspector requests documents to be available, you can ask the Inspector to confirm in writing the exact documents that he/she wishes to review. He/she may not provide this confirmation in writing, but you can ask.***
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Notify the FDA Regulated Research Oversight Program immediately of the inspection. Email: inspection-notification@lists.wisc.edu and member(s) of the Program will be in contact with you. Program representative(s) will help your study team prepare for the visit and ensure all necessary procedures are in place.