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: |

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| --- | --- | --- |
| **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 |
|  | |  |
|  | |  |
|  | |  |
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| 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](mailto: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.