**FDA INSPECTION NOTIFICATION FORM**

**WHEN FDA CALLS TO SCHEDULE A SITE VISIT OBTAIN THE FOLLOWING INFORMATION:**

|  |  |
| --- | --- |
| Call Date: |  |
| Audit Date: | Expected Duration: |
| FDA Investigator contact Information | Name: |
| Telephone:   |
| Title: |
| Additional FDA Investigator’s Names? |  |

**ASK:**

|  |
| --- |
| **Who/what is being inspected?**  |
|  | Clinical Trial(s)/study | Details: |
|  | Principal Investigator/ Sub-Investigator(s) |
|  | Other |
| **Why is the inspection being done?**  |
|  | Routine/Targeted? | Details: |
|  | For cause? |
|  | Follow-up (e.g., previous 483 or warning letter)? |
|  | Bioequivalence  |
|  | Other |
| **What specific personnel need to be available?** |
| **What specific documents need to be available?** |
| **Does the FDA want direct access to the Electronic Medical Record? No Yes** |
| **Does the FDA want any of these documents sent prior to their arrival?**  **No Yes** |
| Address: | How: Overnight Registered Certified |
| Delivery by what date: |

**IMMEDIATELY CONTACT AND SEND NOTIFICATION TO THE FOLLOWING:**

|  |
| --- |
| *Study Specific Contacts* |
|  |
| [ ]  **Principal Investigator**  |
| Date Contacted: |  | Contact Name: |  |
|  |
| [ ]   **Sponsor** |
| Date Contacted: |  | Contact Name: |  |
|  |
| [ ]   **Research Coordinator** |
| Date Contacted: |  | Contact Name: |  |
|  |
| [ ]   **Supervisor/Manager** |
| Date Contacted: |  | Contact Name: |  |
|  |
| *Other Required Contacts* |
|  |
| [ ]   **OSU Office of Responsible Research Practices** |
| Date Contacted: |  | Contact Name: |  |
|  |
| [ ]   **Institutional Review Board of Record** |
| Name of IRB:  |  |
| Date Contacted: |  | Contact Name: |  |
|  |
| [ ]   **Division Director/Department Chair** |
| Date Contacted: |  | Contact Name: |  |
|  |
| [ ]   **College of Medicine Office of Research** |
| Date Contacted: |  | Contact Name: |  |
|  |
| [ ]   **Investigational Drug Service (if applicable)** |
| Date Contacted: |  | Contact Name: |  |
|  |
| [ ]   **Procedural Area/Lab (if applicable)** |
| Date Contacted: |  | Contact Name: |  |