**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: |  |