# NOTICE OF FDA INSPECTION

## Basic information:

|  |  |
| --- | --- |
| Call Date |  |
| FDA Inspector Information(Name, Telephone #, Email) |  |
| Additional FDA Inspector Attendees? (If yes, Names?) |  |
| Inspection Start Date / Time |  |
| Expected Duration |  |

## ask for the following information – *WAIT* *for specific answers. Do not make suggestions*.

### Who / What is being inspected?

*Choose all that apply*

\_\_\_\_\_\_\_ Clinical trial(s)/Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_ Investigator(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Why is the inspection being conducted?

*Select & record any additional information provided by FDA*

\_\_\_\_\_\_\_ Routine (data audit): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_ Directed (for cause): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_ Follow-Up (483, Warning Letter): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### FDA Inspection Requirements?

Does the FDA want specific personnel and/or facilities available for interview/tour? Yes / No

 *circle one*

If yes:

|  |  |
| --- | --- |
| Who | When |
|  |  |
|  |  |
|  |  |

Does the FDA want monitor access to EMR? Yes / No

*circle one*

Does the FDA want specific documents available? Yes / No

*circle one*

|  |
| --- |
| If yes:  |

Does the FDA want any of these documents sent prior to arrival? Yes / No

*circle one*

|  |
| --- |
| If yes, Document(s): |
| Address: | How should materials be sent? *circle one*Overnight Registered Certified e-Portal |
| Delivery by:  |  |

What does the FDA want on List of Studies? PI only / Key Personnel # Years? \_\_\_\_\_\_\_\_\_\_\_\_\_

 *circle one*

*A*re there other inspection requirements? Yes / No

*i.e., COVID protocols, etc.? circle one*

|  |
| --- |
| If yes: |