

FDA Inspection: Prior to the Inspection Tip Sheet



FDA: “We are coming to inspect your study on Monday.”
You: “Now what do I do?”

1

Notify OVPRI’s FDA program at regaffairs@vcu.edu as soon as possible but no later than 24 hours after the initial notification in accordance with compliance notice 17-002: “[Notification Requirement for Research Studies That Are Subject to External Audit or Inspection](#).” Our FDA program will assist before, during and after the inspection.

2

The FDA program will help identify who else needs to be notified of the inspection. This can include, but is also not limited to:

- IRB of record
- Sponsor (as applicable)
- VCUHS floors, pharmacies, labs as applicable to the specific study

We will also talk to the principal investigator and the study team on how to be as prepared as possible; expectations during the inspection and after the inspection; and, how we will provide assistance throughout the week.

3

Identify the location of the records for the study. If it is a closed study and the records are stored at an off-site storage facility, recall the boxes back. Let the company know that it is for an FDA inspection and they will expedite returning them!

4

Reserve a conference room that is clear of documents not associated with the study for the entire week.

Additional information about how to prepare for an inspection, what to expect during and after the inspection can be found in the [FDA program’s manual](#).

Additional questions? Contact us at indide@vcu.edu. We are here to help!