The primary purpose of the U.S. Food and Drug Administration (FDA) is to protect the public health. Specifically, in accordance with 21 CFR 312.62 and 21 CFR 812.145, the FDA has the authority to inspect clinical research sites for compliance with the regulatory requirements. During an FDA inspection, the FDA investigator’s aim is to find evidence of violation. As a result, FDA inspections can be very stressful and anxiety-provoking situations, particularly if the study site investigator has never experienced an FDA inspection, which could contribute to a poor outcome.

Proposed Solution

Having a person with the relevant expertise (an "institutional FDA inspection liaison") who can be present throughout the FDA inspection process, from the moment the FDA notifies the study site that an FDA investigator will be visiting through the completion of the exit interview, may not only alleviate some of the study site investigator’s anxiety, but may also improve the outcome of the inspection.

Clinical sites that are prepared for an FDA inspection are more likely to ensure the best outcome. In 2013, Yale University, as an institution, established a program that offers a “concierge-type” service for Yale site investigators who may be facing an FDA inspection. There are currently seven (7) individuals at Yale (3 individuals within the Yale University Human Research Protection Program (HRPP) and 4 individuals within the Yale Center for Clinical Investigation, Office of Quality Assurance & Training) who have the relevant expertise and training to serve as an institutional FDA inspection liaison for Yale investigators.

An institutional FDA inspection liaison provides the study investigator and his/her study team with assistance from the time that the study investigator learns that the FDA will be coming to conduct an inspection through to the exit interview with the FDA and beyond, if necessary. From the moment the Yale investigator learns that the FDA will be coming to conduct an inspection, the role of an institutional FDA inspection liaison is to prepare the Yale investigator and his/her study team for the FDA inspection.

Prior to the FDA’s arrival, the liaison meets with the Yale study investigator and study team to provide an overview of the FDA inspection process, what to expect during the inspection, and to discuss the conduct of the study at Yale, as well as to review the investigator’s other FDA-regulated studies. Tip sheets and study-specific questionnaires are also provided with information about the FDA inspection process from start to finish, including the possible outcomes of the inspection.

Once the FDA investigator(s) arrives, the liaison assists the Yale study investigator and study team by providing guidance and support throughout the course of the FDA inspection. This assistance includes sitting in the room with the FDA investigator(s) throughout the inspection, assisting with copying any documents required by the FDA investigator(s), and preparing and sending an email summary at the end of each day of the inspection to the study investigator, as well as any other appropriate institutional officials.

The liaison also may serve as an ombudsman for the study investigator during the course of the FDA inspection by interacting with the appropriate institutional offices and departments, including, for example, legal and medical billing, as necessary, to facilitate the inspection process.

Policies & Procedures

In addition to the liaison, we suggest having institutional policies and procedures that specifically address how FDA inspections are handled within the institution. Such policies and procedures may include, without limitation, the following items:

- Information regarding who within the institution the study investigator must notify when he/she is informed that the FDA will be conducting an inspection;
- A statement that the study investigator shall have a designee (i.e., the institutional FDA inspection liaison) present throughout the FDA inspection, including the entrance and exit interviews;
- A statement reminding the study investigators and study team not to sign FDA-prepared affidavits without legal counsel; and
- A reminder that the FDA may request copies of study documents pertaining to the inspection.

Conclusion

We believe that our program of utilizing institutional FDA inspection liaisons has allowed study investigators and their teams to be better prepared for FDA inspections, which may serve to ensure the best outcome.

Statement of Problem

The primary purpose of the U.S. Food and Drug Administration (FDA) is to protect the public health. Specifically, in accordance with 21 CFR 312.62 and 21 CFR 812.145, the FDA has the authority to inspect clinical research sites for compliance with the regulatory requirements. During an FDA inspection, the FDA investigator’s aim is to find evidence of violation. As a result, FDA inspections can be very stressful and anxiety-provoking situations, particularly if the study site investigator has never experienced an FDA inspection, which could contribute to a poor outcome.