**The FDA Is Coming: Where’s My Liaison?**

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**Problem:** The primary purpose of the US 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 regulatory requirements. During an FDA inspection, the FDA inspector’s aim is to find evidence of violation. As a result, FDA inspections can be very stressful and anxiety-provoking situations. Having a person with the relevant expertise who can be present throughout the FDA inspection process, from the moment the FDA notifies the study site that an FDA inspector will be visiting through the completion of the exit interview, may alleviate some of the study site investigator’s anxiety and may improve the outcome of the inspection.

**Program:** Clinical sites that are prepared for an inspection are likely to ensure the best outcome. As an institution, we have established a program which offers a “concierge-type” service for site investigators who may be facing an FDA inspection. We currently have seven individuals (three within the Human Research Protection Program and four within the Office of Quality Assurance and Training) who have the relevant expertise and training to serve as an institutional FDA liaison. From the moment the investigator learns that the FDA will be coming, the role of an institutional FDA inspection liaison is to prepare and assist the investigator and his/her study team. Once the FDA arrives, the liaison assists the study investigator and study team by providing guidance and support throughout the FDA inspection. Such an individual not only provides the study investigator and team with an overview of the FDA process and what to expect during the inspection, but also is present to provide consultation throughout the FDA inspection, up through and including assisting the study investigator in drafting a 483 response letter, if needed. This person also is someone who can serve as an ombudsman for the study investigator by interacting with the appropriate institutional offices /units, including, for example, the legal department or medical billing, as necessary, to facilitate the inspection process.