**Helpful Hints for Before the FDA Inspection**

* Upon arrival, the FDA inspector should present a Notice of Inspection (Form FDA 482) to the PI or his/or designee for signature. They will also present their credentials.
* The PI should be available to meet with the inspector upon arrival unless there are extreme or unforeseen circumstances. The Institutional Official or his/her designee may also request to be present.
* The inspector will explain the intended purpose and scope of the inspection. In addition, the inspector may request that the PI summarize and discuss the study identified for the inspection as well as request a list of all studies for which the PI responsible.
* The FDA inspector may request a tour of the facility areas where the research took place. The escort should accompany the inspector at all times.
* When interacting with the inspector:
* Be polite but limit conversation to the subject matter at hand.
* Listen carefully to any questions posed and only address the question that is asked; do not volunteer any additional information.
* If you do not know the answer, do not speculate. It is acceptable to defer the question to the appropriate individual.
* If there are pauses in the conversation or periods of silence, do not feel compelled to fill these periods of silence with conversation.
* It is recommended that a log be kept of all questions raised and corresponding responses provided during the inspection.
* Typically, the inspector will request files for review. If the FDA investigator requests direct access to UPMC electronic records, the study team should submit a UPMC e-record access request via UPMC Identity Management System ([IMS](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fims.upmc.com%2F&data=02%7C01%7Camy.crippen%40pitt.edu%7C467d9803e36b4714d7cf08d8492a6738%7C9ef9f489e0a04eeb87cc3a526112fd0d%7C1%7C0%7C637339793767119842&sdata=Ja1kbJaoiJXjkP1NW57MkSs2Ea9bi4U6QyQCGQgz1Ro%3D&reserved=0)) on behalf of the FDA investigator. Provide only the files that have been requested. In addition, the inspector may request copies of some documents. These copies should be provided. Note that you should keep track of all documents provided to the inspector. You should also keep a copy of any documents that you provide to the inspector. The inspector’s copies should be stamped ‘Confidential’ and your copies should be stamped ‘Copy.’
* The inspection may include verification of each of the following:
* Who performed various aspects of the protocol,
* Where specific aspects of the protocol were performed,
* Delegation of Authority Log,
* The training provided to the research team to perform the delegated task,
* How and where data were recorded,
* Documentation of consent and the informed consent process,
* Review, causal assessment, documentation and reporting of adverse events,
* Monitoring of the study,
* Communications with the sponsor,
* Comparison of site data with sponsor or FDA data,
* Test article accountability and,
* adherence to the IRB approved protocol.
* During the inspection, one person should be designated as the primary contact person for the inspector. This individual is typically the coordinator or someone who is knowledgeable of the study and is able to coordinate with the PI and other study personnel.
* The PI should set aside time each day to talk with the inspector, as well as being available for any questions that may arise.
* The FDA Investigator will usually hold an exit interview at the conclusion of the inspection. The PI should be present at this meeting along with other appropriate study team members and a designee from the Research Conduct and Compliance Office.

**Helpful Hints for After the FDA Inspection**

* After the inspection, it is recommended that a member of the research team compile a summary of the inspection to include questions asked, records reviewed, copies of documents provided to the inspector, relevant issues raised, and any commitments made to the FDA
* If a 483 was issued, a copy of the 483 must be provided to either the Director of the Education and Compliance Support for Human Subject Research (ECS-HSR) or the Director of Human Research Protection (HRP). The PI should draft a response to the 483. However, this draft must be reviewed by Office of Research Protection leadership prior to it being sent to the FDA. Please refer to HRP guidance for responding to a 483.