FDA Audit Guidance for WMed Staff

Refer to Appropriate FDA Audit Process Documents for Additional Information

“Do” List

* *Wear your ID Badge at ALL times*
* *Be calm, courteous & responsive*
* *Be professional*
* *Speak only for your area of expertise – if you don’t know the answer to a question, tell them that you don’t know, and you will check into it and get back with them with the correct information requested*
* *Be positive in attitude and speak with confidence*
* *Answer questions directly and honestly*

“Don’t” List

* *Do NOT make casual conversation*
* *Do NOT guess or make up an answer*
* *Do NOT lie*
* *Do NOT volunteer more information than necessary to completely answer the question(s)*
* *Do NOT argue or raise your voice*
* *Do NOT provide documents with post-it notes attached, etc.*

Audit Plan Summary

* WMed administration escort – Maureen Owens or an assigned alternate will facilitate and oversee the FDA visit until its completion.
* The FDA inspector will be provided with a quiet area, free from excessive interruptions in which to work.
* During the audit, the WMed administration escort or assigned alternate will provide orientation to the assigned work area for the inspector(s) and if applicable, the primary and/or back-up coordinators will access the study records and files ***only*** related to the study to be inspected. ***Please Note: When possible, ALL binders and/or documents requested by the FDA will be reviewed by Maureen Owens or designee(s) (with the help of the primary & back-up coordinators and/or managerial staff) prior to providing them to the FDA Inspector(s). This will help to ensure there are no sticky notes or wrong patient/regulatory information in another patient’s chart/regulatory binder, etc., prior to FDA review! This review should not impede the inspection.***
* A designated research staff member is available at all times to bring requested materials to the inspector and to make requested copies of documents. The WMed designee makes duplicate copies to be maintained at the site and to show to the sponsor.
* An individual is designated to take notes of the audit, including but not limited to, items reviewed, questions asked, individuals interviewed and responses provided.
* The primary CRC and/or back-up CRC should be available during the entire audit as needed for any questions and/or clarifications related to study and to facilitate ***ALL*** electronic medical record access.
* The primary and/or back-up CRC’s will provide ***only*** what additional information is being requested by the FDA inspector(s).