Inspections

FDA & OHRP Inspections

For routine inspections expect to receive an FDA pre-announced inspection phone call from one to three days in advance of the visit. Please notify the Health Sciences Office of Compliance and Privacy upon receiving the call or letter from the FDA to schedule the inspection.

The following general guidelines are recommended during an FDA inspection from the time the FDA inspector is greeted to the time the exit interview is conducted and a response to the FDA's observations are made.

- Investigators are required to permit the FDA to inspect and copy any records pertaining to the investigation including, in certain situations, those which identify subjects
- Designate a person to serve as escort who will oversee the inspection (usually the research coordinator for the study)
- The escort serves as an institutional monitor as well as guide and general study contact person
- The FDA inspector must not be permitted free access to areas where files are kept

Please contact Health Sciences Office of Compliance and Privacy and the IRB for important information and guidance on Inspections and Audits.

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