Introduction

FDA & OHRP Inspections

For routine inspections expect to receive an FDA pre-announced inspection phone call or letter from one to three days in advance of the visit. Please notify UCLA officials upon receiving the call or letter from the FDA to schedule the inspection. The following officials can provide support and guidance for your inspection: OHRPP Leadership (UCLA IRB), Terra Hughes (CTSI Office of Regulatory Affairs), Maggie Lindenbaum (JCCC Clinical Research Support Services) and the UCLA Office of Compliance. If the FDA will be inspecting a drug study(s), notify the UCLA Department of Pharmaceutical Services, Investigational Drug Section at 310-267-8522.

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 see UCLA Clinical Research Advisory Notices for more information.

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