



GUIDANCE

Study Sponsor Requests for Information and Materials Related to FDA Audits

Study sponsors sometimes request information about whether UW-Madison, its IRBs, or a particular investigator has ever been inspected by the FDA; whether any of the aforementioned have been issued a 483. Sponsors may also request documentation of the inspection, 483, and any resolution (e.g., corrective and preventative action plan (CAPA)). This guidance is designed to assist investigators in responding to such requests.

- 1) UW-Madison will not release institutional- or investigator-related FDA inspectional information.
- 2) UW-Madison IRBs have been the subject of FDA inspections and no 483 has been issued. Investigators may communicate this fact.
- 3) UW-Madison investigators may release FDA inspection materials (e.g., 483 issuances, investigator responses) for **THEIR OWN** prior inspections (i.e., those for which he/she was the clinical investigator under inspection), except as described below.
- 4) Contracts with industry sponsors frequently provide that all information provided to UW-Madison by the sponsor constitutes the sponsor's confidential, proprietary information which may not be disclosed except to individuals who have a need to know in order to conduct the study. Therefore, prior to releasing such information, the UW-Madison FDA Regulated Research Oversight Program will work with UW-Madison investigators to review and appropriately redact* the 483 document, and any other provided document(s), to ensure the released information complies with executed contracts and confidentiality agreements under which the inspected study(ies) were conducted.
 - * Common elements to redact include: information obtained from the study protocol such as study title, name of the study drug, the condition being studied, inclusion/exclusion criteria, study aims, etc.
- 5) Outside of this scope, a sponsor may request inspectional information from the FDA through the Freedom of Information Act.