Policy: FDA Inspections and External Audits

Summary: This policy* describes the required actions to be taken when a member of a UW-Madison study team conducting FDA-regulated human subjects research is notified of an inspection by the Food and Drug Administration (FDA) or audit by another external agency (e.g., National Institute of Health (NIH), Office for Human Research Protections (OHRP), U.S. Department of Agriculture (USDA), etc.). [*Note: Financial audits are out of the scope of this policy]

Successful handling and completion of FDA on-site inspections (or that of other federal agencies evaluating the conduct of FDA-regulated research) is vital to the University’s research mission. Often perceived as an arduous process and time sensitive event, the FDA Regulated Research Oversight Program (henceforth Program) helps support and guide involved investigators and study teams prior to, during and following such federal inspection. Notification and involvement of the Program not only helps individual investigators being audited, it also: assures federal agencies that the University is appropriately engaged in FDA-regulated research oversight; enables individual inspection observations to be trended over time; and allows appropriate cross campus process improvement opportunities to be identified and implemented.

1. The Principal Investigator (PI) and/or other study team member(s) must notify the Program immediately upon notification from the external agency of impending audit or inspection by sending an email correspondence to inspection-notification@lists.wisc.edu. The study team will be asked to provide known information (e.g., PI name, IRB Number, IND/IDE Number(s), date(s) of the planned audit/inspection, type of and/or reason for the audit/inspection, etc.).

2. The PI/study team must work with Program staff and applicable UW-Madison Institutional Representatives throughout the audit/inspection and provide updates to the Program throughout the inspection.

3. The PI/Study team must coordinate scheduling the exit interview or close-out meeting with the auditor/inspector and applicable Program and Institutional Representatives by emailing inspection-notification@lists.wisc.edu. Member(s) of the Program and Institutional Representatives should be present during the exit interview or close-out meeting to answer institutional policy and procedure related questions.

4. If the FDA or external agency is requesting written responses to inspection observations, the PI/study team must provide all written responses to the Program and Institutional Representatives to review and approve prior to submission to the regulatory agency.

5. The PI/study team must promptly provide Program and Institutional Representatives with copies of any further communication(s) to and from the regulatory agency regarding the audit/inspection by emailing inspection-notification@lists.wisc.edu.

Refer to the FDA Inspection Guidance for more information

◊ Subsequent format changes, grammatical corrections (such as spelling), insertion of hyperlinks/hyperlink instructions or insertion of document control version tracking information to this policy may occur without invalidating policy approval status or approval date. Any changes to wording or content requires resubmission of the policy to the FDA Regulated Research Oversight Program – Executive Committee for review and approval.