Policy: FDA Regulated Research Routine Compliance Reviews

Summary: This policy describes the procedures that UW-Madison follows to provide oversight of clinical trials for which a UW-Madison Investigator holds an Investigational New Drug (IND) and/or Investigational Device Exemption (IDE).

1. The UW-Madison FDA Regulated Research Oversight Program (henceforth Program) utilizes Routine Reviews to ensure that clinical trials under an UW-Madison Investigator-held IND or IDE are conducted in compliance with applicable laws, regulations, policies, and guidelines.
   1.1. Clinical trials that meet the following criteria will undergo periodic Routine Reviews:
       1.1.1. Clinical trials for which a UW-Madison investigator holds an IND or IDE; and
       1.1.2. Clinical trials that have been IRB Approved, opened to accrual and enrolled subject(s)
   1.2. Reviews conducted by other internal or external monitoring programs do not take the place of the Routine Reviews conducted by the Program.

2. Investigators shall receive written results of the Routine Review and are responsible for following up with their IRB of record should any reportable events be observed. A copy of the Routine Review report may also be submitted to the IRB of record; however, such submission does not remove the Investigator’s responsibility to submit reportable events to the IRB.

3. Aggregate data obtained from the Routine Reviews are provided to the governance structure for the FDA Regulated Research Oversight Program to enhance the quality, efficiency, and effectiveness of FDA regulated research on campus.

◊ 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.