

POLICY APPROVAL DOCUMENTATION[◇]

Below Policy approved by FDA Program Executive Committee: **April 11, 2018**

Policy: Training for UW-Madison Investigators who hold an IND or IDE

Summary: This policy describes the requirement that UW-Madison Investigators who hold an Investigational New Drug (IND) and/or Investigational Device Exemption (IDE) (i.e., “sponsor-investigators”) must complete training to ensure they are aware of their obligations to conduct research in compliance with FDA requirements.

The conduct of high-quality and compliant FDA-regulated research is paramount to the research mission of the University. Literature suggests, that while faculty may be adept in fulfilling their FDA “investigator” role, they are often unfamiliar with the regulatory role of the “sponsor” (since this is traditionally carried out by pharmaceutical or device manufacturers) and are vulnerable to FDA non-compliance observations if they are not specifically trained for this responsibility. To better support faculty in this dual role, the University is requiring sponsor-investigator training.

1. Initial (baseline) training is required and must be completed prior to initiating a clinical trial under an investigator-held IND or IDE application.
2. Ongoing training will be available and required every three (3) years or more frequently based on regulatory or performance observations or changes in applicable FDA rules.
3. Failure to comply with mandatory training requirements may result in the institution placing the applicable clinical research projects (new or ongoing) hold until such training is completed

[◇] 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.