Policy: UW-Madison IND/IDE Registry

Summary: This policy describes the requirement that UW-Madison personnel register their investigator held Investigational New Drug (IND) or Investigational Device Exemption (IDE) with the UW-Madison FDA Regulated Research Oversight Program.

1. The UW-Madison FDA Regulated Research Oversight Program (henceforth Program) maintains a registry of all UW-Madison investigator-held INDs/IDEs to ensure institutional compliance with FDA requirements and assist investigators in fulfilling their FDA obligations.

   1.1. UW-Madison personnel must initiate the IND/IDE registration process with the Program no later than the time of submission to the FDA. Further guidance on the UW-Madison IND/IDE registration process is available here.

   1.2. UW-Madison personnel must also notify the Program when an IND/IDE has been closed, terminated or withdrawn.

2. UW-Madison personnel seeking guidance on the FDA IND/IDE submission process may consult with the ICTR IND/IDE Consultation Service (I3CS).