

## **FDA Regulated Research**

The Investigational New Drug (IND) or Investigational Device Exemption (IDE) program has three primary objectives:

- To work with UC researchers to facilitate communication with FDA including IND and IDE submissions
- To provide regulatory assistance for Sponsor-Investigators (the person who both initiates an FDA regulated study and has the regulatory responsibility; sponsor in this roles is not related to funding). Also see definition according to [21 CFR 312.3\(b\)](#).
- To serve as a resource and facilitate compliance

To protect researchers and UC, the IND/IDE Assistance Program (IAP) must review IND/IDE applications prior to submissions to FDA whenever a UC researcher is serving as Sponsor-Investigator (per UC HRPP policy III.08). Studies in which a UC researcher is acting as Sponsor-Investigator will be more closely followed using HRPP quality assurance and improvement processes. Please contact the [HRPP office](#) for a comprehensive list of relevant documents.