### Tip #1: What is a Sponsor-Investigator?
- A sponsor-investigator is an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term, as defined in FDA regulations, does not include any entity other than an individual. As the name suggests, a sponsor-investigator assumes the responsibilities of, and must comply with, FDA regulations applicable to both the sponsor and the investigator. These responsibilities include the submission and maintenance of an IND or IDE and the conduct of the study.

### Tip #2: As the Sponsor - Investigator, what am I responsible for?

Your responsibilities as INVESTIGATOR are:
- Ensuring informed consent of each subject is obtained
- Ensuring the investigation is conducted according to the investigational plan
- Personally conducting or supervising the investigation
- Protecting the rights, safety, and welfare of participants
- Preparing and maintaining adequate, current, and complete case histories or records
- Retaining records for two years following the date the marketing application is approved or withdrawn
- Furnishing the required reports to the sponsor, including reports of adverse events and study completion
- Providing timely reports to the COMIRB, including reports of changes in the research activity needed to avoid immediate hazards to participants, unanticipated problems involving risks to participants or others, including adverse events to the extent required by the COMIRB
- Ensuring that changes are not implemented without prospective COMIRB approval, unless required to eliminate immediate hazard to participants
- Complying with all FDA test article requirements
- Adequately maintaining control of test articles, including appropriate tracking documentation for test articles to the extent that such control and documentation are not centrally administered
- Supervising the use and disposition of the test article
- Disclosing relevant financial information
- Ensuring that all associates, colleagues, and employees assisting in the conduct of the investigation(s) are informed about their obligations in meeting the above commitments.

In addition, as the SPONSOR, your responsibilities include:
- Selecting qualified investigators
- Providing investigators with the information they need to conduct the investigation properly
- Ensuring proper monitoring of the investigation
- Submit necessary amendments/supplements to FDA
- Ensuring that the FDA, any reviewing IRB, and all participating investigators are promptly informed of significant new information about an investigation as required by the regulations.
- Preparing and manufacturing the investigational product according to an approved/accepted Good Manufacturing Practice (GMP) plan according to University policy, as applicable
- Maintaining adequate records
- Maintaining proper control and documentation of the investigational product
• Labeling the investigational product in accordance with applicable laws and regulations
• Complying with regulations related to electronic records and electronic signatures, as applicable
• Complying with regulations related to financial disclosure by investigators

Tip #3: What are my options for monitoring the study?

• A sponsor may transfer responsibility for any or all of the obligations listed above to a contract research organization (CRO). Any such transfer must be described in writing. If not all obligations are transferred, the writing is required to describe each of the obligations being assumed by the contract research organization. If all obligations are transferred, a general statement that all obligations have been transferred is acceptable. Any obligation not covered by the written description will be deemed not to have been transferred. This includes monitoring the study.
• The study should have a data and safety monitoring plan that is appropriate for the study.

Tip #4: What Quality Assurance requirements exist?

• The Office of Research Compliance will require that all sponsor-investigators at UCD undergo at least one audit per year by the Quality Assurance and Education team.

Tip #5: For more information, go to:


• Drugs or devices:
  o 21 CFR §11 (Electronic records and electronic signature)
  o 21 CFR §54 (Financial Disclosure by Clinical Investigators)

• Drugs and Biologics:
  o 21 CFR §210 (Current Good Manufacturing Practice In Manufacturing, Processing, Packing, Or Holding of Drugs; General)
  o 21 CFR §211 (Current Good Manufacturing Practice for Finished Pharmaceuticals)
  o 21 CFR §312 (Investigational New Drug Application)
  o 21 CFR §314 (Drugs for Human Use)
  o 21 CFR §320 (Bioavailability and Bioequivalence Requirements)
  o 21 CFR §330 (Over-The-Counter (OTC) Human Drugs Which are Generally Recognized as Safe and Effective and Not Misbranded)
  o 21 CFR §601 (Biologics Licensing)
Devices:
- 21 CFR §812 (Establishment Registration and Device Listing for Manufacturers and Initial Importers Of Devices)
- 21 CFR §812 (Investigational Device Exemptions)
- 21 CFR §814 (Premarket Approval of Medical Devices)
- 21 CFR §820 (Quality System Regulation)
- 21 CFR §860 (Medical Device Classification Procedures)

If you have additional questions or would like assistance, please call the Clinical Research Support Center at (303) 724-1111 or email clinicalresearchsupportcenter@ucdenver.edu