Join Us!

FDA Guidance Core Lecture Series,

Fall 2016

Presented by Jenna Stump, MS, CCRP

Date/Time Location	Title	Description
9/13/16: 9am-10am SOM T501	**How do you know when an Investigational New Drug (IND) application is required?**	All investigators are invited to bring their staff to discuss the UHCMC process for obtaining an investigator held Investigational New Drug (IND) Application and will include: • How an investigator can determine if an IND approval from the FDA is needed. • Elements included in an IND application. • Understanding FDA submission guidelines. • How the approval process works. UH policies related to the use of Investigational drugs.
9/20/16: 9am-10am SOM T501	**Application essentials: Pre-IND and Full IND application**	Investigators are invited to bring their staff to discuss what essentials are needed for a Pre-IND and the Full IND application. Some of the essential items discussed for an Investigational New Drug (IND) Application and will include the following: • Pre-IND advice may be requested for issues related to data needed to support the rationale for testing a drug in humans; the design of nonclinical pharmacology, toxicology, and drug activity studies, including design and potential uses of any proposed treatment studies in animal models; data requirements for an Investigational New Drug (IND) application; initial drug development plans, and regulatory requirements for demonstrating safety and efficacy. • How to fully utilize FDA Guidance Documents to structure and complete your complete IND Application; what is required, where to send it, and who to contact; what research challenges to avoid to complete a Full IND Application; and why research support is essential.

9/27/16: 9am-10am SOM T501	**Maintaining your IND and Investigator Brochure with the FDA**	All investigators are invited to bring their staff to discuss the UHCMC process for maintaining an investigator held Investigational New Drug (IND) Application and Investigator Brochure. Topics of discussion include: • How an investigator should prepare and submit an annual renewal to the FDA; items investigators need to include in the annual report to the FDA; how to determine when a protocol amendment should be filed with the FDA; tips and guidance on how to effectively respond to an FDA protocol inquiry. • The Investigator Brochure (IB) should be reviewed at least annually and revised as necessary in compliance with a sponsor's written procedures; in accordance with GCP, relevant new information may be so important that it should be communicated to the investigators, and possibly to the Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) and/or regulatory authorities before it is included in a revised IB.
10/4/16: 9am-10am SOM T501	**Dietary Supplements and Vitamins: When is FDA Regulation Necessary?**	This session provide information on the FDA's regulatory oversight of dietary supplements and Vitamins, discuss in detail the reasons that would require an FDA review of a supplement or vitamin protocol, and the most effective regulatory pathway with the FDA should their review be required.
10/11/16: 9am-10am SOM T501	**Emergency Use and Expanded Access IND's: Compare and Contrast Session**	This session will go over 21 CFR 312.305, and 21 CFR 312.310 discussing the requirements for both Emergency Use and Expanded Access; their differences and similarities; how the FDA gives authorization; and reporting requirements.
10/18/16: 9am-10am SOM T501	**Closing and/or Transferring an IND**	All investigators are invited to bring their staff to discuss the process for closing and/or transferring of an investigator held Investigational New Drug (IND) Application within UH. UH Research SOP GA 106: Transfer of Protocols Into UH; GA:107 Transfer of Protocols Out of UH) will be discussed.

***All sessions will be located in the School of Medicine T501**