**MANY HATS: the multiple roles and requirements of Sponsor-Investigators conducting FDA regulated clinical research**

With protocols enhanced by the investigators' expertise, experience and academic resources, investigator-initiated trials with FDA regulated products provide valuable data potentially leading to translational research opportunities. However these protocols are held to the same standards and regulations imposed on industry sponsored research which may pose challenges for safety monitoring and data quality.

The IRB must ensure investigators who assume sponsor functions are knowledgeable about the regulatory and institutional requirements this entails. This was initially accomplished by providing a one-on-one assessment and training from the Medical IRB Chair. The Office of Research Integrity (ORI) has now developed a web-based training housed on UK’s Blackboard website entitled ORI0000-NC: Sponsor-Investigator: Clinical Trials with FDA Regulated Products. If you are functioning as the investigator and sponsor for a drug or device protocol IRB policy requires you complete the training. In addition to this course, you may request or the IRB may require an individual consultation with the IRB chair regarding your IND/IDE regulated protocol.

**Device Advice**

In addition to FDA’s Device Advice Website, and the web-based training described above, here are a few reminders regarding research or clinical use of investigational devices:

- If you are serving in the sponsor capacity for an investigational device study, you will need to make a preliminary determination regarding whether the device is significant risk (SR) or non-significant risk (NSR) in order to decide if an Investigational Device Exemption (IDE) should be submitted to the FDA. For guidance, see FDA’s FAQ document or SR/NSR guidance document. Include this information in your IRB application as the IRB has the authority to make the final determination regarding need for an IDE submission. If your study has already received IDE approval from FDA, provide a copy of the FDA’s IDE approval letter with your IRB application.

- Investigators conducting device studies are asked to provide the IRB with details regarding local storage, control and accountability of investigational devices. For example a device may be stored in a locked cabinet in a room accessible only by study personnel. ORI’s Quality Improvement Program web page has Sample Study Logs which you may find useful in maintaining device accountability.

- If you are proposing use of an investigational device which requires electrical connection within the UK Hospital, be aware that the device should be inspected and authorized for use by a Department of Clinical Engineering representative. This requirement is optional for device research conducted in the Kentucky Clinic. For more information about this policy go to the Clinical Engineering website or call 859-323-6383.

- A Humanitarian Use Device (HUD) is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 4,000 individuals in the U.S. per year. HUDs may only be used in a facility after the IRB has approved their use in that facility. When a HUD is used in clinical practice, it is the responsibility of the healthcare provider to obtain IRB approval. Refer to FDA draft guidance released August 5th for questions and answers regarding HUDs.

- Investigational and non-investigational devices used in the hospital require evaluation by the UK technology assessment committee. The e-form is available at http://hosp.uky.edu/forms/rew/rew.asp Contact Value Analysis Director Lorra Miracle, RN with questions (859-323-4745).

- Use of a device in a study raises reimbursement issues based upon the category designation. To receive reimbursement, the Hospital must gain approval from the Medicare Medical Director which is coordinated through the Managed Care Finance department. Contact Elaine Younce for more information at 859-257-9621.

**Conflict of Interest Web Training**

NIH has announced a Web-based tutorial on Financial Conflict of Interest (COI) which reviews the requirements of and responsibilities for compliance with federal COI regulations. It may be accessed at http://grants.nih.gov/grants/policy/coi/index.htm. If you have questions about UK COI policy contact Carol Cole with the Office of Sponsored Projects Administration at 859-257-0579.

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Questions or comments? E-mail us at belinda.smith@uky.edu.