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If you have questions, comments or have a suggestion about how we can improve our human research protection program (HRPP) at UHCMC, send an email to: clinicalresearch@uhhs.com or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

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Guidance from the FDA: Investigational New Drug Application / Investigational Device Exemption Process

When a University Hospital Case Medical Center (UHCMC) investigator initiates and conducts a clinical investigation (**Investigator-Initiated Clinical Trial**) involving the use of a drug device, or biologic, the investigator is responsible for contacting the FDA to determine if an Investigation New Drug approval (IND) or Investigation Device Exemption (IDE) is required.

Investigational New Drug Application (IND):

Under FDA regulations [21 CFR 312.2](#) all clinical investigations that involve drugs (any use of a drug other than the use of a marketed drug) in the course of medical practice must have an IND, unless the drug meets one of the exemptions from the requirement for an IND in [21 CFR 312.2\(b\)](#). (FDA.gov). The following link: [IND Interactive Chart](#) summarizes the IND process, including how the FDA determines that the product is suitable for use in clinical trials (FDA.gov).

Investigational Device Exemption (IDE):

An Investigational Device Exemption (IDE) allows the investigational device to be used in a clinical trial in order to collect safety and effectiveness data required to support a Pre-market Approval application (PMA) or a Pre-market Notification [510(k)] submission to the FDA. All clinical investigations of devices must have an approved IDE or be exempt from the IDE regulation.

In accordance with FDA requirements, it is the policy of UHCMC IRB that a determination of Significant Risk (SR) or Non-Significant Risk (NSR) for a medical device is made prior to consideration of approval of the medical device study. The Significant Risk versus Non-Significant Risk determination must be made by the convened IRB. The criteria for approval of device studies are the same as for any FDA-regulated study. The following link: [Investigational Device Approval](#) provides additional information regarding the FDA Investigational Device Exemption Approval Process.

Assistance is available:

The Center for Clinical Research and Technology Grants and Contract Pre-Award Office offers assistance and guidance with respect to all aspects of the application process. To best assist the investigator, it is recommended that the Grants and Contracts Pre-Award Office is contacted prior to submitting an application for an Investigational New Drug approval or Investigational Device Exemption. For CWRU faculty, the Grants and Contracts Pre-Award Office will contact Dr. Richard Sohn in the CWRU School of Medicine Research Administration Office. A diagram of the process is included as an attachment for your convenience. For additional information contact: Kristen Doud, PhD Kristen.doud@uhhospitals.org at 216-983-5634.

Helpful Links:

<http://www.fda.gov/cder/index.html>

<http://www.fda.gov/cdrh/devadvice/ide/index.shtml>

Education Update:

Please visit the following site for educational opportunities: [Education Calendar](#) (<http://ora.ra.cwr.edu/research/orc/education/onlinecalendar.cfm>). Educational sessions can also be customized to meet the needs of your department, division, or specific research teams. The sessions can be conducted during pre-existing meetings. Please contact Carol Fedor, ND, CCRC at: Carol.Fedor@UHhospitals.org or 216.844.5524.