BASIC PHYSIOLOGICAL RESEARCH

Description

The Food and Drug Administration (FDA) is responsible for regulating devices for human use including Investigational Device Exemptions (IDE). An IDE allows an investigational device (i.e. a device that is the subject of a clinical study) to be used in order to collect safety and efficacy data. In some cases, devices can be used to answer research questions but fall outside of the IDE regulations as is the case with Basic Physiological Research.

The research is considered "Basic Physiological Research" when the following apply:

- Investigating a physiological principle
- No intent to develop the device for marketing
- Not evaluating the safety or efficacy of the device but using the device to address a research question
- No IDE is needed but IRB approval and informed consent should be obtained.

IDE regulations apply to all clinical investigations of devices intending to determine safety and efficacy, evaluate an unapproved or not-cleared device, consider a new indication for use of an approved or cleared device, or to support premarketing application; except as provided in paragraph 21 CFR 812.2(c), Exempted Investigations.

An IDE is not required for an investigation intended only to expand medical knowledge or conduct fundamental research since these investigations are conducted for purposes other than determination of safety and effectiveness for the device at hand.

Research defined as "Basic Physiological Research" is considered to fall outside of the IDE regulations and is therefore not defined within FDA regulation. Although the IDE regulations do not apply to this type of research, IRB approval and informed consent should be obtained prior to initiation of the study.

Points to Address

New Study Application:	1. **HIPAA and the Covered Entity; 3. The Investigational use of a Device:** The investigator should mark "no" if the research meets the definition of Basic Physiological Research.

References & Links

21 CFR 812 Investigational Device Exemptions	*https://www.ecfr.gov/cgi-bin/text-idx?SID=9ff07507fc8138fac4a74d47397d7535&mc=true&node=pt21.8.812&rgn=div5*
21 CFR 812.2 Applicability	*https://www.ecfr.gov/cgi-bin/text-idx?SID=9ff07507fc8138fac4a74d47397d7535&mc=true&node=se21.8.812_12&rgn=div8*
21 CFR 812.3 Definitions	*https://www.ecfr.gov/cgi-bin/text-idx?SID=9ff07507fc8138fac4a74d47397d7535&mc=true&node=se21.8.812_13&rgn=div8*
Preamble to the final rule when Part 812 was published	*Medical Devices; Procedures for Investigational Device Exemptions, Vol. 45 Federal Register 3732, 3735 (Jan. 18, 1980)*
Henley, L. (2013). *How to Put Together and IDE Application*	*https://www.fda.gov/downloads/Training/ClinicalInvestigatorTrainingCourse/UCM378680.pdf*

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

Kalb, S. (2015). *Clinical Trials and Investigational Device Exemptions*	*Slide Presentation:* *https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM466474.pdf* *Transcript: https://www.fda.gov/Training/CDRHLearn/ucm426001.htm*