



<b>SUBJECT:</b>  Use of Devices in Human Subject Research		<b>Policy Number:</b> 10.3.13
	<b>Effective Date:</b> October 19, 2015	<b>Renewal Date:</b> October 19, 2018
	<b>Supersedes:</b> October 21, 2011 August 2, 2010	<b>Page 1 of 6</b>
	<b>Responsible Authorities:</b> Vice President, Research Institutional Review Board Director, Research Integrity	

I. Background

Florida Atlantic University faculty and students conduct a diverse array of human subject research projects, including clinical investigations that involve FDA approved as well as previously approved devices. Device studies involving human subjects must be in compliance with relevant Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) laws and regulations. Investigators planning, designing and implementing clinical studies need to be aware of these FDA and DHHS regulations, as well as FAU requirements.

A device may require an investigational device exemption (**IDE**), a Humanitarian Use Device Exemption (**HDE**), an Abbreviated IDE, or may be exempt from the IDE under 21 CFR 812.2 (c). Specific requirements will depend on the device, its intended use and whether or not its use meets the definition of a significant risk (**SR**) or non-significant risk (**NSR**) device. For example:

- The simplest determination involves a device that meets criteria for *exemption* from IDE requirements. This requires no FDA submission, but in most cases requires IRB approval.
- If a device is determined to be a **non-significant risk device**, then the sponsor follows the Abbreviated IDE requirements outlined under 21 CFR §812.2 (b). This basically consists of IRB approval, labeling, monitoring, and reporting, but submission of IDE paperwork to FDA is not required.
- If a device is determined to be a **significant risk device**, then a full IDE submission to FDA is required along with IRB approval institutional requirements.

## II. Purpose

The purpose of this policy is to ensure that studies conducted by FAU investigators are in compliance with FDA and DHHS regulations and good clinical practices (GCP), and to ensure the protection and welfare of human research participants involved in clinical investigations of devices. In addition, this policy is intended to inform FAU investigators who are planning to conduct human research studies aimed at evaluating the safety or effectiveness of a device--in subjects, controls or their specimens--about applicable FDA and DHHS regulations.

## III. General Statement

Prior to the use of a device in a clinical investigation, the investigator (or sponsor) must assess whether or not an Investigational Device submission is required from the FDA or provide justification and documentation that use of the device is exempt from the IDE requirements. This policy applies to ongoing and planned research involving marketed and investigational devices. This includes: 1) a protocol which will evaluate the safety and/or efficacy of a device in subjects, controls, or their specimens; or 2) a device intended for humanitarian use.

## IV. Policy

All clinical research protocols conducted by FAU faculty and students that involve the use of medical devices must be fully compliant with all FDA and DHHS regulations. The IRB of record will review all clinical research protocols involving devices for evidence of compliance with the applicable laws and regulations.

## V. Definitions (21 CFR 812.3)

**Device:** An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is intended for use in the diagnosis, cure, treatment or prevention of disease. A device does not achieve its intended purpose through chemical action in the body and is not dependent upon being metabolized to achieve its purpose.

**“Custom” device:** a device that meets the following criteria--

- (1) Deviates from devices generally available or from an applicable performance standard or pre-market approval requirement to comply with the order of an individual physician or dentist;
- (2) Is not generally available to, or generally used by, other physicians or dentists;
- (3) Is not generally available in finished form for purchase or for dispensing upon prescription;
- (4) Is not offered for commercial distribution through labeling or advertising; and
- (5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

**510(K) Device:** Devices that are substantially equivalent to other devices that are legally on the market are called 510(K) devices and can be marketed without clinical testing.

**Humanitarian Use Device:** A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year, and where the effort of development generally does

not yield a profit for manufacturers. An HDE allows a HUD to be used without the results of scientifically valid clinical investigation demonstrating that the device is effective for its intended purpose, but it must be used under certain conditions. (21 CFR 814 Subpart H)

**Implant:** a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also “implants”.

**Investigation:** a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

**Investigational device:** a device, including a “transitional device,” that is the object of an investigation.

**Investigational Device Exemption (IDE):** An approved IDE means that the FDA has approved the sponsor’s IDE application for a clinical investigation involving a significant risk device.

**Investigator:** means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

**Monitor:** an individual designated by a sponsor or contract research organization to oversee the progress of an investigation. The monitor may be an employee of a sponsor or a consultant to the sponsor, or an employee of or consultant to a contract research organization. *Monitor*, when used as a verb, means to oversee an investigation.

**Non-invasive:** a diagnostic device or procedure that does not by design or intention: (1) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or (2) enter the ear beyond the external auditory canal, the nose beyond the nostrils, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os (opening of the cervix). Blood sampling that involves simple venipuncture, and the use of surplus samples of body fluids or tissues that are leftover from samples taken for non-investigational purposes, is also considered noninvasive.

**Non-Significant Risk Device (NSRD):** an investigational device that does not meet the definition of a significant risk device.(below) In some cases, these devices may be qualified for an Investigational Device Exemption.

**Significant risk device (SRD)** means an investigational device that:

- (1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- (2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- (3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- (4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

**Sponsor:** a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

**Sponsor-Investigator:** an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.

**Subject (e.g. Participant):** a human who participates in an investigation, either as a recipient of the investigational new drug or as a control. A subject may be a healthy human or a patient with a disease.

**Transitional device:** A device that was regulated by FDA as a new drug before May 28, 1976 before FDA classification systems were changed. An example of such a device is an intraocular lense. [21 CFR 520(l)].

**Unanticipated adverse device effect:** any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

## VI. Accountability

### **The Principal Investigator will be responsible for:**

- Personally conducting and supervising the investigation.
- Not initiating the clinical investigation before obtaining all necessary approvals such as IRB approval and an IDE, if applicable. **(21 CFR 812.110)**
- Informing any potential participant when a test article (device) is being used for investigational purposes.
- Ensuring that proper informed consent is obtained from prospective subjects in accordance with 21 CFR 50, and that such consent is conveyed in an understandable manner. **(21 CFR 50)**
- Ensuring that the protocol has been reviewed and approved by the IRB of record before any participants are consented and enrolled into the study; making changes to the protocol *only after* IRB approval is obtained, except when necessary to protect the safety, rights or welfare of participants.
- Reporting to the sponsor and IRB any unanticipated adverse device effects that occur in the course of the investigation. **(21 CFR 812.46(b); 812.150)**
- Conducting the investigation in accordance with the investigational plan, the signed agreement with the sponsor, applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA. **(21 CFR 812.110; 812.100)**
- Protecting the rights, safety and welfare of the participants in the clinical study, including the confidentiality requirements. **(21 CFR 812.100)**

- Preparing and maintaining adequate documentation/reports as outlined in 21 CFR 812.140 and 812.150, including but not limited to adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual included in the clinical study; maintaining these records for a minimum of 2 years after the FDA approval date, study completion date, or study discontinuation date. **(21 CFR 812.140; 812.150)**
- Disclosing to the sponsor and IRB sufficient, accurate financial information to allow the reporting of complete and accurate financial disclosures; promptly updating this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the study. **(21 CFR 812.110)**
- Supervising device use, and ensuring that the investigational device is used only with subjects under the investigator's supervision. **(21 CFR 812.110; 812.100)**
- Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, returning to the sponsor any remaining supply of the device or otherwise disposing of the device as the sponsor directs. **(21 CFR 812.110)**

**The Study Sponsor will be responsible for:**

- Ensuring that any proposed clinical investigation involving a new device has an approved IDE, IDE exemption, or correspondence from FDA regarding the IDE status, before the study can begin recruiting participants.
- Assuming all other functions of sponsor as outlined in 21 CFR 812 Subpart C.

**The IRB of record will be responsible for:**

- Providing ethical review of any human subject clinical investigation involving a medical device.
- Unless FDA has already made a risk determination for the device study, reviewing the sponsor's SR or NSR determination for every investigational medical device study it reviews and modifying the determination if it disagrees with the sponsor.
- Conducting its standard ethical oversight obligations for the study as outlined in 21 CFR Part 56, FDA Regulations for Institutional Review Boards.

VII. Procedures

***\*Consult with Sponsored Programs or Research Integrity about procedures for initiating a clinical trial of an investigational medical device at FAU.***

- The sponsor or "sponsor-investigator" must make an initial assessment of their study's FDA IDE status and, if applicable, initiate the required IDE documentation prior to submitting an IRB application package. Researchers are strongly encouraged to contact FDA to obtain further guidance prior to the submission of an IDE application, especially if they are uncertain about the proposed study's regulatory status.
- The PI and study team must obtain the FAU required good clinical practices (GCP) training via CITI or another FAU approved GCP training mechanism, prior to initiating a clinical investigation of a medical device.
- The PI must submit, as part of his IRB application package, evidence of an IDE approval number, or documentation of non-significant risk or exemption status. Documentation of NSR or exemption from FDA requirements can be in the form of the FAU IND/IDE assessment tool or written correspondence from FDA. In addition, if the sponsor doesn't

supply a standard protocol and consent template, the PI should complete his protocol and consent form(s) using the FAU templates, including Appendix A for Clinical Investigations and the Informed Consent template for clinical investigations.

- The PI must await FDA, IRB, and Sponsored Programs approval before initiating any data collection for a clinical trial of an investigational medical device at FAU.
- Once the clinical investigation is approved to proceed, the PI is expected to adhere to both the IRB and regulatory obligations outlined under Section V, Accountability.

VIII. Policy Renewal Date  
10/19/2018

IX. References  
45 CFR 46  
21 CFR 812  
21 CFR 56

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POLICY APPROVAL

*Initiating Authority*

Signature:

Date:

Name: Daniel C. Flynn, Ph.D., Vice President for Research

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Executed signature pages are available in the Initiating Authority Office(s)