SOP 502C: CATEGORIES OF RESEARCH – DEVICES

1. POLICY

All human participant research involving devices is reviewed by the IRB in accordance with applicable laws and regulations. For policy information concerning Humanitarian Use Devices, refer to SOP 502F.

The Health Sciences Campus IRB requires that all investigational devices used in human participant research be stored, handled, and dispensed in accordance with governing regulations, University policy, and state and federal law. If the Investigational Pharmacy is not utilized for the dispensing of investigational devices, it is the responsibility of the investigator to assure that dispensing is in accordance with University policy and state and federal law.

Specific Policy

1.1 Clinical Research Involving Devices

1.1.1 Determination of a Valid IDE

When research is conducted to determine the safety or effectiveness of a device, the device has an IDE issued by the FDA, or

The device fulfills the following requirements for an abbreviated IDE:

- The device is not a banned device.
- The sponsor labels the device in accordance with 21 CFR 812.5.
- The sponsor obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval.
- The sponsor ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator’s care, consent under 21 CFR 50 and documents it, unless documentation is waived by the IRB.
- The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
- The sponsor maintains the records required under 21 CFR 812.140(b) (4) and (5) and makes the reports required under 21 CFR 812.150(b) (1) through (3) and (5) through (10);
- The sponsor ensures that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7); and
- The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.

The device fulfills one of the IDE exemption categories:

- A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
- A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the
indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

- A diagnostic device, if the sponsor complies with applicable requirements in 21 CFR 809.10(c) and if the testing:
  - Is noninvasive.
  - Does not require an invasive sampling procedure that presents significant risk.
  - Does not by design or intention introduce energy into a participant.
  - Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

- A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk.

- A custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

As applicable, the IRB requires investigators to provide documentation of an investigational device exemption (IDE) when they submit new research projects for investigator-initiated or industry-sponsored research. The IRB requires investigators to provide documentation of a valid IDE number by submitting a letter from the FDA, a letter from the sponsor, or a commercial protocol with the IDE number.

1.1.2 Definitions

**Significant Risk Device** is defined at 21 CFR 812.3 (m) as a device that presents a potential serious risk to the health, safety, or welfare of a participant and:

A) is intended as an implant;

B) is used in supporting or sustaining human life;

C) is of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise prevents impairment of human health; or,

D) otherwise presents a potential for serious risk to the health, safety, or welfare of the participant.

**Non-Significant Risk Device** is defined at the FDA Information Sheet Guidance, Significant Risk and Non-Significant Risk Medical Device Studies, January 2006, as a device that does not meet the definition above for a significant risk device. These devices pose minimal risk to participants.

1.1.3 Significant Risk (SR) Device vs. Non-Significant Risk (NSR) Device Studies

(A) The difference between NSR device and SR device studies is that NSR device studies have fewer regulatory controls than SR device studies. The IRB acts as the agent of the FDA with respect to review and approval of NSR device studies.

B) When an investigator or a sponsor proposes the initiation of a presumed NSR investigation to the IRB, if the IRB agrees that the device is NSR and approves the research project, the investigation may begin without submission of an IDE application to the FDA. However, if the IRB determines that the device is SR, the research project cannot proceed. The sponsor must notify the FDA that the IRB
has considered the device SR. The research project may proceed as an SR research project following FDA approval of an IDE application and IRB approval. The FDA ultimately determines if a device protocol is SR or NSR.

C) To aid in the determination of the risk status of the device, the IRB shall review information such as reports of prior investigations conducted with the device, the protocol, a description of the participant selection criteria, and monitoring procedures. The sponsor must provide to the IRB the rationale used in making its risk determination. The risk determination is based on the proposed use of a device in the investigation, not on the device alone.

D) The Investigator considers whether or not an IDE is indicated when s/he fills out the IDE sub-form. The IRB considers whether or not an IDE is indicated when reviewing the IDE sub-form the Investigator provides. In the event of a disagreement, the investigator will be requested to submit the study for IDE review with the FDA, which will have final say.

E) The IRB requires investigators to provide the IDE number when submitting new research projects for investigator-initiated or industry-sponsored research.

1.1.4 Investigator Responsibilities for Device Dispensing and Accountability

An investigator shall permit an investigational device to be used only with participants who are under the investigator’s supervision. An investigator shall not supply an investigational device to any person not authorized to receive it.

Upon completion or termination of a clinical research project or the investigator’s part of the investigation, or at the sponsor’s request, the investigator shall return to the sponsor any remaining device, consistent with the terms of the underlying research agreement.

The following accurate, complete, and current records shall be maintained by the investigator:

A) all correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports

B) records of receipt, use, or disposition of the device which relate to:
   - type and quantity of the device, dates of receipt, and the batch number or code mark
   - names of all persons who received, used, or disposed, of each device
   - why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of

The initial research project submission must include a plan for storing, dispensing, and returning (if applicable) the investigational device that is consistent with the underlying research agreement.

2. SCOPE

This SOP applies to all device research submitted to the IRB.

3. RESPONSIBILITY

3.1 The HRPP Director or IRB designee is responsible for maintaining up-to-date review tools for review of research pertaining to devices based on new and evolving applicable regulations and guidelines.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members with adequate submission review training and ongoing guidance and for selecting one Primary and one
Secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with Primary and Secondary reviewers with the relevant expertise or obtains consultation to obtain that expertise.

3.3 The IRB Chair or IRB designee is responsible for conducting appropriate review of research involving devices in consultation with appropriate experts and resources.

3.4 The IRB Reviewer is responsible for conducting appropriate review of research involving devices in consultation with appropriate experts and resources and for utilizing the Reviewer Checklist in reviewing the research project.

3.5 The IRB is responsible for verifying investigators have followed proper procedures for procuring an IDE, IDE exemption/waiver, or HDE, especially for SR devices. It is also responsible for notifying the investigator, the sponsor, or FDA, if applicable, of pertinent information regarding device significant risk.

3.6 The IRB Administrator is responsible for requesting changes to the study protocol from the investigator, based on the IRB review and sending the response of the IRB review to the investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 812
21 CFR 50, 56

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 403: Initial Review - Criteria for IRB Approval
SOP 502F: Humanitarian Use Devices

6. ATTACHMENTS

203-A HSC Reviewer Checklist

7. PROCESS OVERVIEW

7.1 The investigator or investigator’s staff submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The submission with all applicable documents is made available to all IRB members.

7.3 The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received as required, including information about the device, the sponsor’s assessment of SR or NSR, and documentation of an IDE, if applicable. The IRB Administrator also verifies if additional University committee review or information is required. The IRB Administrator communicates with the investigator and/or research staff to obtain any additional information and/or reviews.

7.4 The IRB Administrator assigns the submission either to the appropriate Board agenda or to the IRB Chair/IRB designee.

7.4.1 If to an IRB agenda, the process follows SOP 403: Initial Review – Criteria for IRB Approval.
7.4.2 If to IRB Chair / IRB Designee, the process follows SOP 402: Expedited Review.

7.5 In addition to the requirements outlined in SOP 403, the IRB shall make the following assessments:

7.5.1 If the sponsor indicates the device is NSR, the IRB or IRB Chair / IRB designee shall make a determination of whether to concur with the NSR determination.

7.5.2 The IRB or IRB Chair/Designee evaluates all new device protocols initiated by sponsor-investigators for elements of investigational use of a marketed device.

7.5.3 If a sponsor-investigator is utilizing a marketed device to “expand the device’s safety or efficacy,” the IRB or IRB Chair/Designee understands that a FDA IDE may be required and makes appropriate inquiries with the sponsor-investigator and/or the FDA during review of the research project to determine if an IDE is required.

7.6 Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the Investigator. The IRB Administrator posts the final IRB approval to the next appropriate agenda.

7.7. If an IDE is required, final IRB approval shall not be granted until the IDE process is complete and the necessary documents are received.

7.8. Enrollment into the research project may not commence until all required University committees have completed their review and the research contract is signed, if applicable.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020