

INVESTIGATIONAL DRUG OR DEVICE

SOP #:	412	VERSION #:	1	EFFECTIVE DATE:	6/1/14	SUPERSEDES DOCUMENT:	5/1/09
THIS POLICY PERTAINS TO:			ALL RESEARCH CONDUCTED UNDER THE JURISDICTION OF THE IRB				
RESPONSIBILITY FOR EXECUTING POLICY:		ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB CHAIRPERSON, IRB MEMBERS, INVESTIGATOR					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:						DATE:	3/1/14

1. POLICY

If the principal intent of the investigational use of a test article is to develop information about the product’s safety or efficacy, an Investigational New Drug (IND) or Investigational Device Exemption (IDE) may be required. If an IND or IDE is required, the Investigator proposing to conduct the study must first obtain FDA approval of an IND or IDE application either directly or indirectly via a device or pharmaceutical sponsor. It is also the responsibility of the Investigators to meet the requirements of regulations in [21 CFR 312](#) and [21 CFR 314](#) (investigational drugs) or [21 CFR 812](#) and [21 CFR 814](#) (investigational devices).

2. SPECIFIC POLICY

2.1 Investigator Responsibilities

2.1.1 The Investigator will need to determine if an IND is necessary. An IDE or IND is not required in the following types of studies, however IRB approval is required:

- A clinical study involving a Non Significant Risk (NSR) device;
- A clinical study involving the use of a drug or device in a diagnostic procedure that simply confirms the diagnosis made by another medically established diagnostic product (e.g. blood grouping serum, reagent red blood cells, or antihuman globulin);
- A clinical study involving a marketed drug or biologic as follows:
 - The results of which are not intended to be reported to FDA in support of new indication for use or to support any other significant change in the labeling for the drug;
 - The results of which are not intended to support a significant change in the advertising for the product;
 - Does not involve a change en route of administration, dosage level, or subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
 - Is conducted in compliance with the requirements for IRB review and informed consent (21 CFR parts 50 and 56, respectively)
 - Is conducted in compliance with the requirements concerning the promotion and sale of drugs (21 CFR 312.7); and
 - Is not intended to invoke 21 CFR 50.24

2.1.2 The Investigator will need to submit the IND or IDE assignment letter to the IRB. If there is debate regarding the need for an IND, the IRB will require that the PI contact the FDA to obtain written documentation that an IND is not necessary. When conditions stated in 21 CFR 312.2(B) (1) have been met, then an IND is not necessary.

2.1.3 If the Investigator plans on holding the IND or IDE, the Investigator will be required to meet with the Associate Vice President for Research and Economic Development and the IRB Chairperson to review how the Investigator plans to meet the sponsors requirements according to 21 CFR 312 and 21 CFR 314 for an IND and 21 CFR 812 and 21 CFR 814 for an IDE. The Investigator will need to put the plan into writing and submit it to the IRB for final approval. The plan needs to include, but not limited to: good manufacturing practices, test article storage, labeling, distribution, accountability, site study monitoring, conflict of interest, and periodic reports to the FDA.

2.1.4 The Investigator is responsible for assuring the IRB that the investigational drugs and devices are stored in a safe and secure manner.

2.1.5 The Investigator is responsible for assuring the IRB that there are appropriate plans for inventory control, storage, monitoring and dispensing of the test articles (drugs, biologics, or devices).

2.1.6 The Investigator will obtain informed consent for studies involving an IND or IDE. The consent form will identify the test article as investigational and will inform the participants that the FDA may inspect the research records.

2.2 Research Conducted to Determine Safety and/or Effectiveness of a Device

2.2.1 When research is conducted to determine the safety or effectiveness of a device, the IRB will determine that the device fulfills the 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.
- 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.

2.2.2 When research is conducted to determine the safety or effectiveness of a device, the IRB will determine that the device fulfills one of the following 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.

2.3 IRB Review

2.3.1 The IRB will review each protocol that uses drugs, biologics or devices to see if an IND or IDE has been received or required. If one is required, it is the Investigators responsibility to obtain the FDA assignment letter. The IRB will use the guidance provided by [21 CFR 312.2](#) and [21 CFR 812.2](#) in determining if an IND or IDE is required. If an IND or IDE is required, the PI must provide documentation of a valid IND number on the Human Subjects Review Form.

2.3.2 The IRB will review protocols involving investigational devices to determine if the device is a Significant Risk device (SR) or a Non- Significant Risk device (NSR). If the IRB determines that the research involves a SR device, an IDE is necessary. If the Investigator does not already have an IDE, the Investigator will be notified. Investigators must include in their proposal plans for inventory controls for storage, monitoring, and dispensing of investigational drugs or devices that meets appropriate standards.

2.3.3 For research involving a new drug or new device, before issuing approval for the research, IRB staff verify that any pending IND or IDE submissions have passed the 30 calendar day FDA clearance period (unless there is an earlier notification by FDA that studies may begin), or stipulate in the approval letter that research must not commence – including recruitment, obtaining informed consent, and screening participants – until the IND or IDE is in place.

2.3.4. Studies involving an IND or IDE will undergo initial and continuing review at a convened meeting of the IRB that includes at least one physician or pharmacist unless the study meets the criteria for expedited review (i.e. all treatment components are complete, in follow-up only, data analysis only).

3. RESPONSIBILITY

The IRB Chairperson and Associate Vice President for Research and Economic Development are responsible for meeting with an Investigator who is plans on holding an IND or IDE.

IRB members are responsible for reviewing IND or IDE protocol submissions, and verifying that the valid IND or IDE number is documented on the Human Subjects Review Form.

4. APPLICABLE REGULATIONS AND GUIDELINES

- 21 CFR parts 50 and 56
- 21 CFR 50.24
- 21 CFR 312.2(b)
- 21 CFR 312.7
- 21 CFR 312, 314, 812, 814

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>IRB Chairperson and Associate Vice President for Research and Economic Development</i>	Meet with the Investigator (who plans on holding the IDE or IND) to assure that the Investigator understands and puts into writing the plan that he/she is to act as the “sponsor” and will adhere to the sponsor responsibilities outlined in 21 CFR 312, 314, or 812, 814
<i>IRB Members</i>	Review the IRB submission, including the plan (if Investigator holds the IND) for covering the responsibilities outlined in 21 CFR 312, 314, or 812, 814.