SOP 1.2.2 Drug and Device Studies – FDA Regulated Research

General Description:

This document describes the requirements and procedures for research that is subject to the regulations of the Food and Drug Administration (FDA). All studies involving investigational or unlicensed test articles (drugs, devices, or biologics) in human subjects must have oversight by an Institutional Review Board (IRB) to ensure compliance with relevant DHHS Regulations 45 CFR 46, the Guidelines for Good Clinical Practices adopted by the FDA, and FDA regulations 21 CFR part 56.

The following are terms, as defined by the FDA, which are used throughout this document:
Drug: A substance recognized by an official pharmacopoeia or formulary. A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. A substance (other than food) intended to affect the structure or any function of the body.
Device: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man and not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Biologic: Biological products, or biologics, are medical products. Many biologics are made from a variety of natural sources (human, animal or microorganism). Like drugs, some biologics are intended to treat diseases and medical conditions. Other biologics are used to prevent or diagnose diseases.
Test article: The term includes drugs (including botanicals, biologicals, and gene therapy, and genetically derived products that meet the definition of a "drug"), and medical devices for human use under investigation.

Procedures:

All initial requests for IRB approval of a study that includes the use of an investigational drug or device, or an off-label use of a drug or device, will be reviewed and approved by the convened IRB as part of full committee review. Studies involving drugs and devices that are already FDA approved, being used in accordance with their approved indications, may be reviewed by the IRB through expedited review or full committee review.

Investigators must plan for the storage, control, and dispensing of drugs and devices in compliance with the FDA regulations to ensure only authorized investigators have access to the test articles and that the test articles are only used on subjects who have provided consent. This includes proper labeling of the investigational drug or device.

1. The researchers must submit the documents required by the IRB for the use of investigational drugs and devices in a new submission through IRBNet. The required documents include the Application form, any investigator or sponsor correspondence with the FDA, Consent document(s), recruitment materials, and Addendum D for investigational drugs and/or Addendum E for investigational Devices.

2. The convened IRB will review the submitted materials to determine if the submitted protocol meets the criteria for approval and the IRB will complete the corresponding new protocol transmittal form and worksheet for the drug or device under investigation, to document how the criteria are met.
    a. If the test article has an Investigational New Drug (IND) number or an Investigational Device Exemption (IDE) the IRB will need to confirm the numbers are valid by the investigator providing the IRB with one of the following: Sponsor protocol imprinted with the IND or IDE number or written communication from the FDA to the sponsor or to investigators documenting the IND or IDE number (required if an investigator listed on the protocol is the holder of the IND or IDE).
    b. The researchers must also include a copy of their package insert and/or label for investigational devices and a copy of the investigator brochure for drugs as part of their submission for the IRB to review.
3. The convened IRB will verify if the drug or device has an IND or IDE, respectively. If the PI is requesting that the drug or device be exempt from IND or IDE requirements, the convened IRB will discuss the conditions for exemption from the IND/IDE requirements. The IRB will determine whether or not the Investigator's justification meets the criteria for exemption from the requirements by reviewing the relevant Addendums along with completing the relevant Worksheets for drug and device review.
4. For investigational devices where the PI is requesting an exemption from IDE requirements, the board must vote on the risk level of the device. If the board determines a device poses a significant risk (SR) to subjects, then the investigator will be required to contact the FDA to obtain an IDE before the research can begin. If the board determines that the device poses a non-significant risk (NSR), then the researchers can begin their research once IRB approval is obtained without a requirement to obtain an IDE.
   The following criteria are considered when determining whether or not a device poses significant risks to subjects:
    a. The device is intended as an implant and presents a potential for serious risk to health, safety, or welfare of the participant.
    b. The device is purported or represented to be for use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a participant.
    c. The device is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents the potential for serious risk to the health, safety, or welfare of the participant.
    d. The device otherwise presents a potential for serious risk, safety, or welfare of a participant.
5. The NSR/SR determination will be documented on the Device Worksheet during IRB review of the protocol. If at any future point in time the FDA disagrees with the NSR/SR determination made by the IRB, the researchers and IRB must follow the FDA determination instead.
6. Once the study involving an FDA regulated test article is approved, the researchers must follow the SOPs: 2.6.1. Continuing Review, 2.6.4. Amendments, and 2.6.5. Reportable events as they would for any other protocol. The researchers must also comply with reporting requirements of the FDA for drugs and devices as well as follow Good Clinical Practices during the conduct of their research.

Related Forms, Guidance, and SOPs:

- Addendum D – FDA Regulated Drugs
- Addendum E – FDA Regulated Devices
- Worksheet: Drugs (IRB use only)

- Worksheet: Devices (IRB use only)
- 45 CFR 46.111
- 25 CFR part 56
- New Application form
- 2.5.1 Full Board Review
- 2.6.1. Continuing Review
- 2.6.4. Amendments
- 2.6.5. Reportable events
- FDA Reporting Requirements
- Good Clinical Practices

Responsibility:

Execution of SOP:
Principal Investigator
Study Team Members
IRB Staff
IRB Members

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

Date First Effective:	August 24, 2016
Revision Date:	[DATE]
Current Version #:	1

Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	August 24, 2016
Laurie Meamber	IRB Chairperson	August 24, 2016