



<b>Policy Name: Review of Research Involving Drugs or Biological Drug Products Policy and Procedures</b>			
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**I. POLICY**

This policy defines the use of drugs and biological drug products in human clinical research settings. MUSC policy requires that investigators obtain approval of and adhere to FDA regulations regarding those studies that involve FDA regulated products (drugs, devices or biologics) identified by the review conducted by the IRB Administrators, IRB Chair and IRB members. Principal investigators must provide the IRB with sufficient information for evaluation of the drug’s effectiveness and analysis of risk.

**II. DEFINITIONS**

As used in this document, human-subjects research encompasses activities that meet the DHHS definitions of **research** and **human subject** and/or the FDA definitions of **clinical investigation** and **human subject**. Definitions for the following terms may be found in HRPP Program Guide Section 1.3 - Definitions of terms:

- A. **Research**
- B. **Human subject**
- C. **Intervention**
- D. **Interaction**
- E. **Private information**
- F. **Clinical investigation**
- G. **Botanical drug products**
- H. **Investigational new drug**
- I. **Radioactive drug**
- J. **Sponsor**
- K. **Sponsor-investigator**

**III. PROCEDURES**

- A. The principal investigator (PI) will submit a completed Investigational New Drug (IND) Drug Information Sheet A if the research involves an investigational drug using a sponsor’s IND. The principal investigator will submit documentation of the IND number.
- B. The PI will submit a completed Investigational New Drug (IND) Drug Information Sheet A if the research involves a MUSC investigator-

sponsored IND submission. The attachments will include a completed FDA form 1571 with all required attachments and FDA form 1572 with a current curriculum vitae attached.

C. The PI will submit a completed Drug Information Sheet B when the research involves the use of drug which is exempt from the 21 CFR 312.2 FDA requirement for an IND:

1. Exemption 1:

- a) The drug product is lawfully marketed in the United States.
- b) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
- c) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.
- d) The investigation does not involve a route of administration or dosage levels or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
- e) The investigation is conducted in compliance with 21 CFR 50 and 56.
- f) The investigation is conducted in compliance with requirements of 21 CFR 312.7.

2. Exemption 2:

- a) A clinical investigation is for an *in vitro* diagnostic biological product that involves one or more of the following:
  - (1) Blood grouping serum.
  - (2) Reagent red blood cells.
  - (3) Anti-human globulin.
- b) The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.

- c) The diagnostic test is shipped in compliance with 21 CFR 312.160.
- 3. Exemption 3:
  - a) A drug intended solely for test in vitro or in laboratory research animals if shipped in accordance with 21 CFR 312.160.
- 4. Exemption 4:
  - a) A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND.
- D.** If the principal investigator states that use of the marketed drug(s) in a manner not currently approved by the FDA does not significantly create risk to subjects, current supporting literature must be attached.
- E.** The IRB administrator will include a minimum of one PharmD or MD IRB member as a primary reviewer of a protocol involving the use of a marketed drug(s) in a manner not currently approved by the FDA.
- F.** The IRB Chair may consult with the PharmD or MD IRB members prior to the convened meeting. Additional supporting literature may be requested or the PI may be asked to attend the meeting to discuss the use of the drug(s).
- G.** The Board will make the decision if the principal investigator must query the FDA regarding the need for an IND given the nature of the research and the drug(s) use.
- H.** The Board may table the protocol or approve the protocol with the contingency that the approval will not be released until documentation from the FDA is received that an IND is not required or an IND number is received. The Board's discussion and decision will be documented in the meeting's minutes.
- I.** All inpatient studies must be coordinated through the Investigative Drug Services and the investigator is responsible for following all procedures as defined in "Research Involving Investigational Medications Conducted within MUSC Medical Center Policy and Procedures".
- J.** The PI is responsible for assuring the investigative drugs are only used in the IRB approved research study and under the direction of the study investigator.

- K.** Outpatient studies may be coordinated through the Investigational Drug Services but if the PI can provide adequate storage and control over the distribution of investigational drug supplies, the investigator(s) may be exempt from the pharmacy handling requirement and would thus assume responsibility for the services that would have been provided by the IDS. These areas may also be audited by the IDS at any time to assess compliance. The PI is responsible for assuring the IRB there are appropriate plans for inventory control, storage, monitoring and dispensing of the test articles (drugs, biologics, or devices).
- L.** Investigational drugs for Treatment IND, compassionate use and other emergency uses will be handled by the Investigative Drug Services upon request.
- M.** The PI or appropriate member of the research team will obtain informed consent and the consent form will identify the test article as investigational and will also inform the participants that the FDA may inspect the research records.

#### **IV. PROCEDURES SPECIFIC TO VA RESEARCH**

- A.** The investigator is responsible for informing pharmacy service through the use of VA Form 10-1223 that the IRB and R&D Committee approvals have been obtained.
- B.** The investigator is responsible for providing the pharmacy with a signed copy of the VA consent form 10-1086 to document each participant's consent to participate in the study.
- C.** **VA Research:** The investigator is responsible for informing the Chief of Pharmacy Service and the R&D Committee when a study involving investigational drugs has been terminated.

#### **V. REFERENCES**

- A.** Code of Federal Regulations Title 21 : [21 CFR 312](#)