

## **SOP 603C: Food and Drug Administration (FDA)**

### **1. POLICY**

The Institutional Review Board shall operate pursuant to the regulations of the United States Food and Drug Administration (FDA) in the review of human research involving investigational drugs, biologics, or devices.

The purpose of IRB review is to assure, both in initial and by continuing review, that appropriate steps are taken to protect the rights and welfare of humans participating in the research. In accordance with FDA regulations, the IRB has the authority to approve, require modifications of (to secure approval), or disapprove research.

The definition of research encompasses activities that are “clinical investigations” and involve “human subjects” as those terms are defined by FDA regulations.

The HSC IRB shall review all FDA-related research for all University campuses. SOP 403: Initial Review provides additional guidance.

#### **Specific Policies**

##### **1.1 FDA Regulations**

The HSC Campus IRB shall operate pursuant to the FDA regulations 21 CFR Part 50, 54, 56, 312, 600, 601, and 812.

###### **1.1.1 Noncompliance and Participant Safety**

The Human Research Participant Protection (HRPP) Director or designee shall act as the liaison between the FDA and the University. The HRPP Director or designee shall report incidences of serious or continuing non-compliance or unanticipated problems involving risk to participants or others to the FDA per SOP 308: Reporting to Regulatory Agencies and Institutional Officials.

###### **1.1.2 Guidance from the FDA**

A representative of the HRPP Office may communicate with the FDA to evaluate research projects when appropriate or to seek guidance as needed.

###### **1.1.3 FDA Audits**

The FDA has the authority to audit the IRB records and/or Investigators on a routine basis or for cause. FDA field investigators interview University officials and examine the IRB records to determine compliance with FDA regulations.

When the FDA notifies the Institution of an IRB site visit, the HRPP Director or designee shall notify the Director of Compliance who immediately notifies the Institutional Official and Legal Counsel.

### **2. SCOPE**

This SOP applies to interactions between the FDA and the HRPP Office.

### **3. RESPONSIBILITY**

3.1 The HRPP Director or designee is responsible to provide guidance regarding FDA regulations to IRB staff, IRB members, and investigators.

3.2 The IRB staff is responsible to immediately notify the HRPP Director or designee when contacted by the FDA for an audit or site visit. . The HRPP Director or designee is

responsible to immediately notify the Director of Compliance and the Institutional Official and Legal Counsel.

3.3 The HRPP Education Coordinator includes information regarding the FDA regulations and research in the HSC IRB education program. Investigators are responsible for making themselves familiar with these regulations.

3.4 The Investigator is responsible to copy the IRB on all correspondence to and from the FDA.

#### **4. APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 50 and 56.

21 CFR 312, 600, 601 and 812.

FDA INFORMATION SHEETS-GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS AND CLINICAL INVESTIGATORS, 1998 UPDATE

#### **5. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 308: Reporting to Regulatory Agencies and Institutional Officials

SOP 403: Initial Review

#### **6. ATTACHMENTS**

603-C-A Government Agents and Compliance Policy – 11/17/2008 Memorandum from Anil Gallahalli, University General Counsel

#### **7. PROCESS OVERVIEW**

7.1 The HSC IRB reviews all FDA-regulated research in accordance with the applicable FDA regulations.

7.2 The HRPP Director or designee acts as the liaison between the FDA and the Institution.

7.3 The HRPP Director or designee may communicate with the FDA to evaluate research projects when appropriate or to seek guidance as needed. The HRPP Director shall consult the Director of Compliance prior to communicating with the FDA and include the Director of Compliance in telephone calls with the FDA as appropriate.

7.4 The HRPP Director or designee is the point of contact for an FDA Audit. The HRPP Director notifies the Director of Compliance of the FDA audit and directs IRB staff as indicated.

7.5 The HRPP Director or designee retains written form FDA-483, if such a form is drafted. The HRPP Director or designee informs the Director of Compliance of the FDA preliminary findings of audit.

7.6 The HRPP Director maintains FDA documents on file at the IRB Office in accordance with the State Universities and Colleges General Records Disposition Schedule.

**APPROVED BY:** \_\_\_\_\_ **DATE:** 09/09/2016

**NEXT ESTABLISHED REVIEW DATE:** AUGUST 2018