

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.

Specific Policies

1.1 FDA Regulations

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

A. Noncompliance and Participant Safety

The Human Research Participant Protection (HRPP) Director shall act as the liaison between the FDA and the University. The HRPP Director shall report incidences of non-compliance or participant safety concerns to the FDA per SOP 308, Reporting to Regulatory Agencies and Institutional Officials.

B. 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.

C. 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 institutional 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 policy applies to interactions between the FDA and the HRPP Office.

3. RESPONSIBILITY

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

The IRB staff is responsible to immediately notify the HRPP Director or designee of a communication from the FDA. The HRPP Director or designee is responsible to

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

The Education Coordinator includes information regarding the FDA regulations and research in the HSC IRB education program.

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

4. APPLICABLE REGULATIONS AND GUIDELINES

- 45 CFR 46.
- 21 CFR 50 and 56.
- 21 CFR 312, 600 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

6. ATTACHMENTS

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

7. PROCESS OVERVIEW

- 7.1 The IRB reviews all FDA-regulated research in accordance with the FDA regulations.
- 7.2 The HRPP Director 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 Director of Compliance shall be consulted prior to communicating with the FDA, and may be included in telephone calls as appropriate.
- 7.4 The HRPP Director or designee is the point of contact for an FDA Audit. The HRPP Director notifies the Compliance Officer 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 Compliance Officer of the FDA preliminary findings of audit.
- 7.6 The HRPP Director maintains FDA documents on file at the IRB Office.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012