

SOP: 602A
OFFICE OF COMPLIANCE

1. POLICY

The University's Office of Compliance, under the direction of the Director of Compliance, shall be responsible to oversee, monitor, and assist the University in its efforts to (i) raise awareness regarding ethical issues; (ii) improve compliance training and quality improvement and review functions; and (iii) obtain adherence to the highest standards of conduct.

The Office of Human Research Participant Protection (HRPP) operates under the direction of the Director of Compliance. All HRPP policies shall be reviewed and approved by the IRB Executive Committee (Chair/Vice Chair Committee) and the Director of Compliance prior to implementation. The HRPP Director shall initiate and implement approved policies and policy revisions.

The Office of Compliance shall identify and disseminate new information that may affect human research protection. This information may include new or revised state or federal laws, regulations, or guidance, as well as institutional policies and procedures.

The Office of HRPP shall function independently and free from outside influence. The HRPP and IRB staff, through the HRPP Director, shall report incidents of influence that directly affect the review process and the protection of human participants to the Director of Compliance.

Specific Policies

1.1 Compliance Issues

Compliance issues are addressed in SOP 903, Non-compliance/Scholarly Misconduct.

1.2 Office of HRPP

The Director of Compliance reviews HRPP policies, assists the HRPP Director in policy development, and serves on the IRB Executive Committee.

2. SCOPE

This policy applies to interactions between the Office of Compliance and the Office of HRPP.

3. RESPONSIBILITY

The Director of Compliance shall be responsible to oversee the Office of HRPP.

The Director of Compliance advises the HRPP Director on compliance issues. The HRPP Director informs the Director of Compliance regarding noncompliance issues and implements policies pertaining to the HRPP Program.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

21 CFR 56

University of Oklahoma, Compliance and Quality Improvement Program

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 903, Non-compliance/Scholarly Misconduct.

6. ATTACHMENTS

None.

7. PROCESS OVERVIEW

7.1 Compliance

Refer to SOP 903, Non-compliance/Scholarly Misconduct, for process overview.

7.2 Office of HRPP

One of the IRB Chairs acts as the Chair of the IRB Executive Committee meetings. The Director of Compliance is a member of the IRB Executive Committee. These meetings are held once each month to review and update HRPP policy as needed. The HRPP Director or IRB Education Coordinator is responsible for meeting preparation and completion of the meeting minutes.

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

NEXT ESTABLISHED REVIEW DATE: MAY 2012