

SOP: 602B
OFFICE OF LEGAL COUNSEL

1. POLICY

The Institution's Office of Legal Counsel shall, upon request, provide legal guidance to the HRPP Director and IRB Chairs in the conduct of the Office of Human Research Participant Program activities. Legal Counsel shall be available to interpret and provide advice to the HRPP Director and IRB Chairs regarding relevant laws and policy pertaining to research involving human participants. Relevant law and policy may include federal and Oklahoma constitutional law, federal and Oklahoma statutes, other applicable law and regulations, and University policy.

Specific Policies

1.1 Consultation

Legal Counsel may be consulted by the HRPP Director and IRB Chairs when issues arise that require legal or policy interpretation. Legal Counsel shall, upon request, provide advice to the HRPP Director and IRB Chairs when new law or policy may affect research. In doing so, Legal Counsel assists the HRPP Office in remaining compliant with applicable University policies, laws, and regulations.

1.2 Records Requests

The HRPP Office shall respond to requests from Legal Counsel for Open Records Requests as well as other requests for information concerning research activity conducted at the University.

2. SCOPE

These policies and procedures apply to all aspects of the HRPP Program.

3. RESPONSIBILITY

The HRPP Director brings issues for discussion to Legal Counsel, and provides information to Legal Counsel at their request.

The IRB Chairs discuss issues with the HRPP Director and consult with Legal Counsel as needed.

Legal Counsel, upon request, advises the HRPP Director and IRB Chairs with respect to University policy, federal and Oklahoma constitutional law, federal and Oklahoma statutes, other applicable law and regulations, and University policy.

The HRPP Office cooperates with Legal Counsel in records requests and other requests for information involving human participant research activity.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.101 (f)

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

None.

7. PROCESS OVERVIEW

7.1 The HRPP Director meets with Legal Counsel as legal or policy issues arise. Issues such as acceptable language for informed consent documents, determinations regarding exculpatory language, and local and state laws are among the items for which legal advice may be requested.

7.2 The HRPP Director acts upon or disseminates the advice of Legal Counsel to the HRPP and IRB staff. The HRPP Director documents advice given from Legal Counsel for reference as needed.

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

NEXT ESTABLISHED REVIEW DATE: MAY 2012