1. POLICY

The University’s Office of Legal Counsel shall, upon request, provide legal guidance to the HRPP Director or designee 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 or designee and IRB Chairs regarding relevant laws and policy pertaining to research involving human participants. Relevant law and policy may include federal and Oklahoma case law, federal and Oklahoma statutes, other applicable law and regulations, and University policy.

Specific Policies

1.1 Consultation

The HRPP Director or designee and IRB Chairs may consult Legal Counsel when issues arise that require legal or policy interpretation or resolution of conflicts of laws. Legal Counsel shall, upon request, provide advice to the HRPP Director or designee 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.

1.3 Notice to the Office of Legal Counsel

The HRPP staff shall notify the Office of Legal Counsel of audits or investigations conducted by state or federal agencies or law enforcement that involve the HRPP or IRB and will include the Office of Legal Counsel in any responses to such agencies.

2. SCOPE

This SOP applies to all aspects of the HRPP Program.

3. RESPONSIBILITY

3.1 The HRPP Director or designee may bring issues for discussion to Legal Counsel and provide information to Legal Counsel at their request.

3.2 The IRB Chairs discuss issues with the HRPP Director or designee and consults with Legal Counsel as needed.

3.3 Legal Counsel, upon request, advises the HRPP Director or designee and IRB Chairs with respect to University policy, federal and Oklahoma case law, federal and Oklahoma statutes, other applicable law and regulations, and University policy as well as conflicts of law.

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

3.5 The HRPP staff shall, as soon as possible, notify the Office of Legal Counsel of audits or investigations conducted by state or federal agencies or law enforcement that involve the HRPP or IRB and will include the Office of Legal Counsel in any responses to such agencies.
4. APPLICABLE REGULATIONS AND GUIDELINES
   45 CFR 46.101 (f)

5. REFERENCES TO OTHER APPLICABLE SOPS
   None

6. ATTACHMENTS
   None

7. PROCESS OVERVIEW
   7.1 The HRPP Director designee meets with Legal Counsel as legal or policy issues or audits or investigations 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 or designee acts upon or disseminates the advice of Legal Counsel to the HRPP Office and IRB chairs. The HRPP Director or designee documents advice given by Legal Counsel for reference as needed.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020