

## **SOP: 1101**

### **OKLAHOMA STATE LAWS PERTAINING TO RESEARCH**

#### **1. POLICY**

Federal regulations require the IRB to conduct research in compliance with applicable state law. The IRB and investigators must comply with Oklahoma state laws as they pertain to human participant research. This policy outlines Oklahoma State laws pertaining to research activities.

##### **Specific Policies**

#### **1.1 Research Involving Protected Populations**

##### **1.1.1 Emancipated Minors**

Under 63 O.S. §2601, any minor who is married, has a dependent child, or is emancipated (released from parental or guardian control and is not supported by the parents or guardian) may consent to certain health services. Health services do not include research or experimentation except when the research or experiment is an attempt to preserve the life of that minor or research as approved by an appropriate review board involved in the management of reportable diseases.

##### **1.1.2 Cognitively Impaired Individuals**

Under 63 O.S. §3201A, under certain conditions consent of a cognitively impaired individual to participate in a research project may be obtained from a legal guardian, attorney-in-fact with health care decision authority, or a family member (in the following order: spouse, adult child, either parent, adult sibling, or a relative by blood or marriage). However, if cognitively impaired individuals were legally competent to express permission or prohibition prior to becoming cognitively impaired, the legal guardian or family member cannot override the individual's previously expressed permission or prohibition.

##### **1.1.3 Fetal Materials**

Under 63 O.S. §1-735, research on fetal tissue resulting from an abortion is prohibited. An abortion is defined as the purposeful termination of a pregnancy with an intent other than to produce a live birth or remove a dead unborn child.

The use of fetal tissue resulting from a spontaneous miscarriage for research purposes is not specifically prohibited.

#### **1.2 Other Applicable State Law**

There are other state laws that could extend to the research being conducted. For example, state law requires that any person having reason to believe that a child under the age of 18 is a victim of abuse or neglect shall report the matter to the Department of Human Services. This state law is not specific to or even related to

research; however, during the conduct of research, personnel could become aware of child abuse or neglect and would be required to report the abuse under state law.

**2. SCOPE**

These policies and procedures apply to all other SOPs.

**3. RESPONSIBILITY**

It is the responsibility of the investigator to conduct research according to Oklahoma State laws.

It is the responsibility of the IRB Chairs to approve only research that is in compliance with Oklahoma State laws.

**4. APPLICABLE REGULATIONS AND GUIDELINES**

Oklahoma Statutes, 63 O.S. §2601  
Oklahoma Statutes, 63 O.S. §3201  
Oklahoma Statutes, 63 O.S. §1-735

**5. REFERENCES TO OTHER APPLICABLE SOPS**

This SOP affects all other SOPs.

**6. ATTACHMENTS**

None.

**7. PROCESS OVERVIEW**

- 7.1 Legal Counsel provides guidance on Oklahoma law to HRPP Director and/or IRB Chairs.
- 7.2 The HRPP Director and/or IRB Chair or designee contacts or meets with Legal Counsel as needed for guidance on the application of Oklahoma State law pertaining to human research.
- 7.3 The HRPP Director acts upon or disseminates the guidance of Legal Counsel to the IRB Chair and/or IRB staff and documents advice for reference as needed.

**APPROVED BY:** \_\_\_\_\_ **DATE:** 09/01/2009

**NEXT ESTABLISHED REVIEW DATE:** MAY 2012