

14.0 Investigator Responsibilities

14.1 Qualifications of a Principal Investigator

All KUMC or KULC faculty may exercise the privilege of being named as principal investigator (PI) or project director on proposals. Unclassified professional staff may qualify to serve as PI as approved by the appropriate chair, dean, or hospital administrator.

14.2 Principal Investigator Responsibilities

KUMC requires that principal investigators understand the responsibilities associated with conducting human subject research. Investigators must comply with federal regulations, state and local laws, and institutional policies. They are responsible for training staff and for conducting the research. Ultimately, they are responsible for the safety of the human subjects participating in the study. Specifically, investigator requirements include the following:

- adhere to federal regulations, state and local laws, institutional policies, and HSC procedures regarding the safety and protection of human subjects
- provide HSC with complete and up-to-date study protocol
- ensure the protocol submitted to HSC is identical to the proposal for funding for extramural or intramural support
- conduct the study without deviation from the HSC-approved protocol, except in circumstances of direct threat of harm to the subject
- inform HSC of any updates or modifications to the protocol; secure HSC approval of any protocol changes prior to implementation except when a delay in implementation would place subjects at risk
- obtain prior HSC approval for the involvement of all study personnel
- engage in recruitment practices that are fair and non-coercive
- ensure that no subject is enrolled without adequate informed consent
- clarify to the subjects which study activities are standard of care and which are conducted for research purposes
- monitor study data to assess subject safety
- promptly report to the HSC the events described in SOP 5.3
- report all adverse events to sponsors, data monitoring entities or appropriate federal agencies as required;
- submits continuing review reports to HSC in a timely fashion so that HSC approval does not lapse
- maintain documents as required by federal, state and university policies/procedures; make these records available for inspection by appropriate authorities;
- personally conduct the study or supervise study conduct by sub-investigators
- assure that all sub-investigators are adequately trained not only to perform the assigned study procedures but also to protect human subjects
- comply with applicable regulations on handling and dispensing investigational drugs or devices
- complete periodic training, as required by the University, to remain up-to-date on federal regulations, KUMC policies and procedures, and compliance expectations
- store and handle research data in accordance with regulations on privacy and confidentiality

- after study completion, maintain study data in accordance with the KUMC Policy on Research Records Retention

14.3 State Laws Related to Research

KUMC investigators, HRPP staff, and HSC members must comply with the following state laws when they apply to research. KUMC Office of Legal Counsel provides assistance in determining the applicability of Kansas state laws to human subjects research. The Office of Legal Counsel is also consulted when KUMC investigators are responsible for conducting studies in other states. When an investigator indicates on the HSC application that he or she is conducting the study in states other than Kansas or Missouri, the HRPP Director contacts the Office of Legal Counsel for guidance. The Office of Legal Counsel works with the investigator to ensure a clear understanding of any applicable laws. Applicable laws may include, but are not limited to, determinations about who is considered a child, who can serve as a guardian and who can serve as a legally authorized representative in the state where the research is being conducted. If the HSC is the IRB of record for a study being conducted outside Kansas or Missouri, fulfillment of requirements in the other state is a condition of HSC approval.

KSA 38-101 defines a minor as an individual less than eighteen (18) years of age. Unless the requirement is waived by the HSC, investigators must obtain parental permission and child assent for research subjects who are minors.

KSA 65-102 lists the infectious diseases that must be reported to the Secretary of Health and Environment. Examples include testing for HIV status, Hep B, and tuberculosis. When the research subject must undergo testing for infectious diseases as part of the research trial, the research consent should inform the subject that positive results will be reported to the state. The subject should be notified of the test results and offered an opportunity for counseling services.

KSA 38-1522 requires licensed health care providers to report physical, mental or emotional abuse to state agencies. If the research protocol involves a likelihood that abuse may be identified, the research consent form must inform potential subjects of the investigator's reporting obligations under state law. When the HSC approves a research protocol under a Certificate of Confidentiality (CoC), the HSC will require that subjects be informed that the CoC does not affect the investigator's obligation to report abuse to state authorities.

KSA 59-3075 specifies the types of research for which legal guardians may provide consent on behalf of wards. A legal guardian is an individual or corporation appointed by the court. In appointing a guardian, the court will give priority to a durable power of attorney (DPOA). If a DPOA has not been designated, then the court may consider a family member or outside party. A guardian can be an individual or a corporation. The state statutes outline the duties of a guardian as having the custody and control of the ward, and to provide for the ward's care, treatment, habilitation, education, support and maintenance. A guardian shall at all times act in the best interests of the ward and shall exercise reasonable care, diligence and prudence. A guardian may consent to research that involves a significant risk of harm only if (a) the research is intended either to preserve the life of the ward, or to significantly improve the quality of life of

the ward, or to assist the ward to develop or regain significant skills or abilities; and (b) the guardian has been fully informed concerning the potential risks and benefits of the proposed research and has specifically consented to the research.

KSA 65-4974 outlines the conditions under which surrogate consent may be used for research. The law applies to decisions made on behalf of adults or emancipated minors who are incapable of giving informed consent for a research protocol. The ability of these decision-makers to consent on another's behalf only applies when the clinical research is being conducted by a licensed physician with medical staff privileges and when the research has been reviewed and approved by an institutional review board. If these two conditions are met, a hierarchy of preferred decision-makers may provide informed consent on behalf of the incapacitated individual. Surrogate consent must be appropriately documented. The HSC provides a surrogate consent form template that lists the hierarchy of preferred decision-makers.

References:

45 CFR 46.111
21 CFR 56.111
KSA 38-101
KSA 65-102
KSA 38-1522
KSA 59-3075
KSA 65-4974