I. Purpose:
This policy outlines the qualification and responsibilities for being an Principal Investigator. The policy also explains applicable state laws that apply to human subject research.

Regulation and Guideline Reference(s):
45 CFR 46.111
21 CFR 56.111
KSA 38-101
KSA 65-102
KSA 38-1522
KSA 59-3075
KSA 65-4974

II. Procedure:

18.1 Qualifications of a Principal Investigator

I. All KUMC or KULC faculty may exercise the privilege of being named as principal investigator (PI) or project director on proposals. University or hospital staff may qualify to serve as PI as approved by the appropriate chair, dean, center director or hospital administrator. Qualifications for principal investigators are determined by the HRPP in consultation with the Institutional Official, RAC and other institutional leaders.

II. Faculty members from affiliated institutions may be approved to serve as principal investigator on a KUMC project on a case-by-case basis.

18.2 Principal Investigator Responsibilities

I. 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. The responsibilities of the principal investigator are listed in detail in SOP 1.5.XI.

18.3 State Laws Related to Research

I. KUMC investigators, HRPP staff, and IRB members must comply with the following state laws when they apply to research. KUMC Office of the General Counsel provides assistance in determining the applicability of Kansas state laws to human subjects research. The Office of the General Counsel is also consulted when KUMC investigators are responsible for conducting studies in other states. When an investigator indicates on the IRB application that he or she is conducting the study in states other than Kansas or Missouri, the HRPP Director contacts the Office of the General Counsel for guidance. The Office of the General 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 IRB 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 IRB approval.

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

III. 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.

IV. 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 IRB approves a research protocol under a Certificate of Confidentiality (CoC), the IRB will require that subjects be informed that the CoC does not affect the investigator's obligation to report abuse to state authorities.

V. 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.

VI. 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 IRB 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

Attachments:

Approval Signatures

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<th>Date</th>
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<tr>
<td>Steffani Webb: Vice Chancellor for Administration</td>
<td>12/10/2019</td>
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<tr>
<td>Lisa Hoebelheinrich: Chief Compliance Officer</td>
<td>12/10/2019</td>
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<td>Annie Fors: QA Director</td>
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<td>Karen Blackwell: Director HRPP</td>
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Applicability

KU Medical Center, KU SoM Wichita