Kansas Law on Research Consent by Surrogate Decision-Makers

In 2004, the Kansas legislature passed KSA 65-4974, which delineated the group of individuals who may act as surrogate decision-makers for participation in clinical 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.

This law supports the priority of decisions made by either a legal guardian or an attorney-in-fact with the authority to make health care decisions for the individual. However, if neither such role exists, or if the person acting in the capacity cannot be contacted using reasonably diligent efforts, informed consent for research participation may be granted by a family member in the following order:

1. The adult or emancipated minor's spouse, unless they are legally separated;
2. An adult child;
3. A parent;
4. An adult relative by blood or marriage.

The law places a caveat on surrogate decision-making, in that no decision in favor of research participation may be made if the incapacitated person has previously expressed contrary wishes, either orally or in writing.

KUMC researchers who are conducting clinical trials that may involve incapacitated persons must use a consent form that has been specifically designed for such purpose. The consent form must be reviewed and approved by the Institutional Review Board (IRB) prior to its use. A consent template is available on our website.

For further information about the state law or about IRB requirements, please contact the IRB Office at 913.588.1240.