217.5404 Written informed consent required for treatment with investigational drug, biological product, or device.

(1) A patient or a patient's legal guardian shall provide written informed consent for treatment with an investigational drug, biological product, or device.

(2) At a minimum, the written informed consent shall include:

(a) An explanation of the currently approved products and treatments for the disease or condition from which the patient suffers;

(b) An attestation that the patient concurs with the treating health care provider's belief that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

(c) Clear identification of the specific investigational drug, biological product, or device that the patient is seeking to use;

(d) A description of the potentially best and worst outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome;

(e) A statement that the patient's health plan or third-party administrator and provider shall not be obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device unless they are specifically required to do so by law or contract; and

(f) A statement that the patient understands that the patient shall be liable for all expenses related to the use of the investigational drug, biological product, or device and that the liability for expenses extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

(3) The description of potential outcomes required under subsection (2)(d) of this section shall:

(a) Include the possibility that new, unanticipated, different, or worse symptoms may result and that the proposed treatment may hasten death; and

(b) Be based on the treating health care provider's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

(4) The written informed consent shall be:

(a) Signed by:

1. The patient;

2. A parent or legal guardian, if the patient is a minor; or

3. A legal guardian, if a guardian has been appointed for the patient; and

(b) Attested to by the patient's treating health care provider and a witness.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 65, sec. 4, effective June 29, 2017.

Formerly codified as KRS 217.5407.