217.5401 Definitions for KRS 217.5401 to 217.5408.

As used in KRS 217.5401 to 217.5408:

(1) "Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, protein other than a chemically synthesized polypeptide, allergenic product or analogous product, or arsphenamine or derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings;

(2) "Device" has the same meaning as in KRS 217.015;

(3) "Drug" has the same meaning as in KRS 217.015;

(4) "Eligible patient" means an individual who meets the requirements of KRS 217.5403;

(5) "Health care provider" means a licensed physician, a licensed advanced practice registered nurse, or a licensed physician assistant;

(6) "Health facility" has the same meaning as in KRS 216B.015;

(7) "Investigational drug, biological product, or device" means a drug, biological product, or device that:

   (a) Has successfully completed Phase I of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration; and

   (b) Remains under investigation in a United States Food and Drug Administration-approved clinical trial;

(8) "Terminal illness" means a progressive disease or a medical or surgical condition that:

   (a) Entails significant functional impairment;

   (b) Is not considered by a treating health care provider to be reversible even with administration of a treatment currently approved by the United States Food and Drug Administration; and

   (c) Without life-sustaining procedures, will result in death; and

(9) "Written informed consent" means a written document that meets the requirements of KRS 217.5404.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 65, sec. 1, effective June 29, 2017.