Instruction Sheet for Informed Consent for Investigational Drug, Product, or Device

R.C. 4731.97(I) requires the State Medical Board to create a template of an informed consent form for investigational drugs, products, or devices. The template on the State Medical Board website is a model to be used by a treating physician in securing a patient's informed consent to treatment of a terminal condition with an investigational drug, product, or device.

"Terminal condition" means any of the following conditions, if irreversible, incurable, and untreatable through a method of treatment approved by the United States food and drug administration: (a) a progressive form of cancer; (b) a progressive neurological disorder; (c) a progressive musculoskeletal disorder; or (d) a condition that, based on reasonable medical standards and a reasonable degree of medical certainty, appears likely to cause death within a period of time that is relatively short but does not exceed twelve months.

A treating physician may make formatting or stylistic changes to the form, but must include all of components required by R.C. 4731.97 which is linked on the Medical Board website under the Statutes tab.