144E.2 Definitions.

As used in this chapter:

1. *"Eligible facility"* means an institution operating under a federalwide assurance for the protection of human subjects pursuant to 42 U.S.C. §289(a) and 45 C.F.R. pt. 46, and subject to the federalwide assurance laws, rules, policies, and guidelines including renewals and updates.

2. *"Eligible patient"* means an individual who meets all of the conditions specified under paragraph *"a"* or *"b"*:

a. (1) Has a terminal illness, attested to by the patient's treating physician.

(2) Has considered and rejected or has tried and failed to respond to all other treatment options approved by the United States food and drug administration.

(3) Has received a recommendation from the individual's physician for an investigational drug, biological product, or device.

(4) Has given written informed consent for the use of the investigational drug, biological product, or device.

(5) Has documentation from the individual's physician that the individual meets the requirements of this paragraph *"a"*.

b. (1) Has a life-threatening or severely debilitating illness, attested to by the patient's treating physician.

(2) Has exhausted all other United States food and drug administration-approved treatment options by contraindication, potential or previous treatment failure, or actual or potential adverse reaction.

(3) Has received a recommendation from the individual's physician for an individualized investigational treatment, based on an analysis of the patient's genomic sequence, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products such as enzymes and other types of proteins, or metabolites.

(4) Has given written informed consent for the use of the individualized investigational treatment.

(5) Has documentation from the individual's physician that the individual meets the requirements of this paragraph *"b"*.

3. *"Individualized investigational treatment"* means a drug, biological product, or device that is unique to, and produced exclusively for use by, an individual patient, based on the individual patient's own genetic profile, and is provided in a manner that is consistent with a federalwide assurance for the protection of human subjects. *"Individualized investigational treatment"* includes but is not limited to individualized gene therapy, antisense oligonucleotides, and individualized neoantigen vaccines.

4. *"Investigational drug, biological product, or device"* means a drug, biological product, or device that has successfully completed phase 1 of a United States food and drug administration-approved clinical trial but has not yet been approved for general use by the United States food and drug administration and remains under investigation in a United States food and drug administration-approved clinical trial.

5. *"Terminal illness"* means a progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating physician to be reversible even with administration of treatments approved by the United States food and drug administration, and that, without life-sustaining procedures, will result in death.

6. *"Written informed consent"* means a written document that is signed by the patient, a parent of a minor patient, or a legal guardian or other legal representative of the patient and attested to by the patient's treating physician and a witness and that includes, at a minimum, all of the following:

a. If the patient is an eligible patient as specified in subsection 2, paragraph *"a"*:

(1) An explanation of the products and treatments approved by the United States food and drug administration for the disease or condition from which the patient suffers.

(2) An attestation that the patient concurs with the patient's treating physician in believing that all products and treatments approved by the United States food and drug administration are unlikely to prolong the patient's life.

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

(4) A description of the best and worst potential outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by use of the proposed investigational drug, biological product, or device. The description shall be based on the treating physician's knowledge of the proposed investigational drug, biological product, or device in conjunction with an awareness of the patient's condition.

(5) A statement that the patient's health plan or third-party administrator and provider are not 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.

(6) A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements.

(7) A statement that the patient understands that the patient is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that this liability 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.

b. If the patient is an eligible patient as specified in subsection 2, paragraph *"b"*:

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

(2) An attestation that the patient concurs with the patient's treating physician in believing that all currently approved and conventionally recognized products and treatments are unlikely to prolong the patient's life.

(3) Clear identification of the specific proposed individualized investigational treatment that the patient is seeking to use.

(4) A description of the best and worst potential outcomes of using the individualized investigational treatment and a realistic description of the most likely outcome. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by use of the proposed individualized investigational treatment. The description shall be based on the treating physician's knowledge of the proposed individualized investigational treatment in conjunction with an awareness of the patient's condition.

(5) A statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the individualized investigational treatment, unless they are specifically required to do so by law or contract.

(6) A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the individualized investigational treatment and that hospice care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements.

(7) A statement that the patient understands that the patient is liable for all expenses consequent to the use of the individualized investigational treatment and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the individualized investigational treatment states otherwise.

2017 Acts, ch 130, §2; 2025 Acts, ch 80, §1
Referred to in §144E.3
Section amended