

Part 3. Individualized Treatments.

§ 90-325.30. Definitions.

The following definitions apply in this Part, unless the context requires otherwise:

- (1) Eligible facility. – Any institution operating under Federalwide Assurance for the Protection of Human Subjects in accordance with 45 C.F.R. § 46 and 42 U.S.C. § 289(a).
- (2) Eligible patient. – An individual who meets all of the following criteria:
 - a. Has a life-threatening or severely debilitating illness, attested to by a treating physician.
 - b. Has, in consultation with a treating physician, considered all other treatment options currently approved by the United States Food and Drug Administration.
 - c. Has received a recommendation from the treating physician for use of an individualized investigational drug, biological product, or device for treatment of the life-threatening or severely debilitating illness.
 - d. Has given informed consent in writing to use of the individualized investigational drug, biological product, or device for treatment of the life-threatening or severely debilitating illness or, if the individual is a minor or is otherwise incapable of providing informed consent, the parent or legal guardian has given informed consent in writing to use of the individualized investigational drug, biological product, or device.
 - e. Has documentation from the treating physician that the individual meets all of the criteria for this definition. This documentation shall include an attestation from the treating physician that the treating physician was consulted in the creation of the written, informed consent required under this Part.
- (3) Individualized investigational drug, biological product, or device. – A drug, biological product, or device that is unique and produced exclusively for use for an individual patient, based on their own genetic profile, including individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines.
- (4) Institution. – As defined in 45 C.F.R. § 46.102(f).
- (5) Life-threatening or severely debilitating illness. – As those terms are defined in 21 C.F.R. § 312.81.
- (6) Written, informed consent. – A written document that is signed by an eligible patient; or if the patient is a minor, by a parent or legal guardian; or if the patient is incapacitated, by a designated health care agent pursuant to a health care power of attorney, that at a minimum includes all of the following:
 - a. An explanation of the currently approved products and treatments for the eligible patient's life-threatening or severely debilitating illness.
 - b. An attestation that the eligible patient concurs with the treating physician in believing that all currently approved treatments are unlikely to prolong the eligible patient's life.
 - c. Clear identification of the specific individualized investigational drug, biological product, or device proposed for treatment of the eligible patient's terminal illness.
 - d. A description of the potentially best and worst outcomes resulting from use of the individualized investigational drug, biological product, or device to treat the eligible patient's life-threatening or severely

debilitating illness, along with a realistic description of the most likely outcome. The description shall be based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the eligible patient's life-threatening or severely debilitating illness and shall include a statement acknowledging that new, unanticipated, different, or worse symptoms might result from, and that death could be hastened by, the proposed treatment.

- e. A statement that eligibility for hospice care may be withdrawn if the eligible patient begins treatment of the life-threatening or severely debilitating illness with an individualized investigational drug, biological product, or device and that hospice care may be reinstated if such treatment ends and the eligible patient meets hospice eligibility requirements.
- f. A statement that the eligible patient's health benefit 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 drug, biological product, or device, unless specifically required to do so by law or contract.
- g. A statement that the eligible patient understands that he or she is liable for all expenses consequent to the use of the individualized investigational drug, biological product, or device and that this liability extends to the eligible patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.
- h. A statement that the eligible patient or, for an eligible patient who is a minor or lacks capacity to provide informed consent, that the parent or legal guardian consents to the use of the individualized investigational drug, biological product, or device for treatment of the life-threatening or severely debilitating illness. (2024-36, s. 1.)