§ 90-325.16. Definitions.

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

(1) Adult stem cell. – An undifferentiated cell that is (i) found in postnatal differentiated tissue and (ii) able to renew itself and differentiate to yield all or nearly all of the specialized cell types of the tissue from which the cell originated.

(2) Clinical trial. – A research study in which one or more human subjects are prospectively assigned to one or more interventions using adult stem cells administered under United States Food and Drug Administration protocols for Investigational New Drugs or Investigational Device Exemptions.

(3) Eligible patient. – An individual who meets all of the following criteria:
   a. Has a severe chronic disease or terminal 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 investigational adult stem cell treatment for the severe chronic disease or terminal illness.
   d. Has given informed consent in writing to use of the investigational adult stem cell treatment 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 investigational adult stem cell treatment.
   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.

(4) Investigational adult stem cell treatment. – Adult stem cell treatment that meets all of the following criteria:
   a. Is under investigation in a clinical trial and being administered to human participants in that trial.
   b. Has not yet been approved for general use by the United States Food and Drug Administration.

(5) Severe chronic disease. – A condition, injury, or illness that meets all of the following criteria:
   a. May be treated.
   b. Is never cured or eliminated.
   c. Entails significant functional impairment or severe pain.

(6) Terminal illness. – As defined in G.S. 90-325.1(3).

(7) 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 severe chronic disease or terminal illness.
   b. An attestation that the eligible patient concurs with the treating physician in believing that all currently approved treatments are unlikely to alleviate the significant impairment or severe pain

associated with a severe chronic disease or unlikely to prolong the life of an eligible patient with a terminal illness.

c. Clear identification of the specific investigational adult stem cell treatment proposed for treatment of the eligible patient's severe chronic disease or terminal illness.

d. A description of the potentially best and worst outcomes resulting from use of the investigational adult stem cell treatment to treat the eligible patient's severe chronic disease or terminal 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 severe chronic disease or terminal 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 terminal illness with an investigational adult stem cell treatment 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 investigational adult stem cell treatment, 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 investigational adult stem cell treatment and that this liability extends to the eligible patient's estate, unless a contract between the patient and provider of the investigational stem cell treatment 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 investigational adult stem cell treatment for treatment of the severe chronic disease or terminal condition. (2019-70, s. 1.)