

1 §1169.3. Definitions

2 As used in this Subpart, the following terms have the meaning ascribed to
3 them in this Section:

4 (1) "Eligible patient" means a person to whom all of the following criteria
5 apply:

6 * * *

7 (d)(i) Has given his consent in writing for the use of the investigational drug,
8 biological product, or device; or, if he is a minor or lacks the mental capacity to
9 provide consent, a parent or legal guardian has given consent in writing on his
10 behalf.

11 (ii) A person who can understand and comprehend spoken English but is
12 physically unable to talk or write may be deemed as meeting the criteria of this
13 Subparagraph if he is competent and able to indicate consent by other means.

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15 (2)(a) "Investigational drug, biological product, or device" means a drug,
16 biological product, or device that has successfully completed phase one of a United
17 States Food and Drug Administration approved clinical trial, but has not been
18 approved for general use by the United States Food and Drug Administration and
19 remains under investigation in a clinical trial.

20 (b) Notwithstanding Subparagraph (a) of this Paragraph, for purposes of this
21 Subpart, "investigational drug, biological product, or device" shall include any
22 device possessing the following characteristics regardless of whether it has
23 successfully completed phase one of a United States Food and Drug Administration
24 approved clinical trial:

25 (i)(aa) If of a robotic nature, the device is designed such that any failure in
26 a multitude of continuous tests of its internal subsystems should cause motion to
27 stop, consistent with the Guidelines For Robotics Safety from the Occupational
28 Safety and Health Administration of the United States Department of Labor
29 (Directive Number STD 01-12-002).

- (2) The device has all of the following features for intentional control:
 - (a) The motion of the device responds to specific controls from the user.
 - (b) The device has no machine state in which motion continues without a specific command from the user.
- (3) The device has an emergency stop button which allows an assistant to force the motion of the device to stop.

(Amends R.S. 40:1169.2(3) and 1169.3(1)(d) and (2))