

§ 511.3

in section 572 of the act, subject to the provisions of § 516.125 of this chapter.

[40 FR 13823, Mar. 27, 1975, as amended at 41 FR 48268, Nov. 2, 1976; 42 FR 15675, Mar. 22, 1977; 50 FR 7517, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 52 FR 8847, Mar. 19, 1987; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992; 62 FR 40599, July 29, 1997; 72 FR 69121, Dec. 6, 2007; 77 FR 25359, Apr. 30, 2012; 82 FR 61446, Dec. 28, 2017]

§ 511.3 Definitions.

As used in this part:

Contract research organization means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.

Investigator means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. “Sub-investigator” includes any other individual member of that team.

Sponsor means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

Sponsor-Investigator means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.

[77 FR 25359, Apr. 30, 2012]

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AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 360ccc, 371, 379e, 381.

EFFECTIVE DATE NOTE: At 89 FR 51782, June 18, 2024, the authority citation was amended, effective Dec. 18, 2025.