

Additional Requirements for Sponsor-Investigator

Excerpted from CU IRB SOPs (v4.2) and expanded

Sponsor-Investigator (S-I) means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational product is administered, dispensed, or used. When an Investigational New Drug (IND) exemption or Investigational Device Exemption (IDE) is held by the individual who is conducting the clinical investigation, the individual is considered to be an S-I.

When a Principal Investigator (PI) is acting as a Sponsor-Investigator, additional consideration must be given as to how compliance with FDA requirements will be maintained. The Columbia University [FDA Compliance Program for FDA-regulated Human Subjects Research](#) outlines the institutional oversight of S-I research.

The [IND-IDE Assistance Program](#) (IAP) has been established within the [Clinical Trials Office](#) (CTO) to provide education, training and support to S-Is with respect to FDA regulations, and to help ensure appropriate documentation and trial monitoring to satisfy regulatory requirements. S-Is are encouraged to consult with CTO early in the development of their protocol. The Clinical Trials Monitoring and Assistance Program (CTMAP) provides support with respect to monitoring S-I research.

When any study will be conducted by an S-I, the submission for IRB review must include the “Form of Notice by CU Faculty IND/IDE Holder” documenting that the Department Chair and the S-I both have provided commitment that adequate resources will be provided that will permit the conduct of the study in compliance with FDA regulatory requirements.

The IRB and CTO work together, under the provisions of the FDA Compliance Program , to ensure that regulatory requirements are met.

Definitions and Regulatory References

Research with Drugs:

A *drug* is defined in the current federal Food, Drug and Cosmetic Act as:

- a. articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them;
- b. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
- c. articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
- d. articles intended for use as a component of any articles specified in clause a, b, or c; but does not include devices or their components, parts, or accessories.

For S-I research with investigational drugs, additional consideration must be given to how compliance with FDA requirements for both the sponsor and investigator will be maintained. The submission for IRB approval must include a plan for both conduct and monitoring of the study in accordance with 21 CFR 312.

Research with Biologics:

Biological products, like other drugs, are used for the treatment, prevention or cure of disease in humans. In contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biological products are generally derived from living material--human, animal, or microorganism-- are complex in structure, and thus are usually not fully characterized.

Section 351 of the *Public Health Service (PHS) Act* defines a biological product as a “virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, ... applicable to the prevention, treatment, or cure of a disease or condition of human beings.”

For S-I research with biologics, additional consideration must be given to how compliance with FDA requirements for both the sponsor and investigator will be maintained. The submission for IRB approval must include a plan for both conduct and monitoring of the study in accordance with 21 CFR 312 (INDs) and 21 CFR 600 (Biologics).

Research with Devices:

A *medical device* is defined in the current federal Food, Drug and Cosmetic Act as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- a. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;
- b. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- c. intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

For S-I research with a medical device, additional consideration must be given as to how compliance with FDA requirements for both the sponsor and investigator will be maintained. The submission for IRB approval must include a plan for both conduct and monitoring of the study in accordance with 21 CFR 812.

Human Subject:

FDA defines a *subject* as a human who participates in an investigation, either as a recipient of the investigational new drug or as a control. A subject may be a healthy human or a patient with a disease. (21 CFR 312)

It is important to note that the FDA definition of “human subject” in 21 CFR 812 (IDE regulations) differs from the definition in 21 CFR 312 (IND regulations). *Subject* is defined in 21 CFR 812 as a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.

DHHS defines a *human subject* as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. (45 CFR 46.102 (f))