

Sponsor-Investigator IND Scenarios

Scenario 1: One Sponsor-Investigator

Dr. Jekyll holds an IND and is Principal Investigator of the protocol conducted under that IND. She is a “true” Sponsor-Investigator who both initiates and conducts a study.

Scenario 2: One Sponsor Plus One Investigator

Dr. Watson holds an IND.

Dr. Moreau, a colleague at the same institution, is Principal Investigator of the protocol conducted under Dr. Watson’s IND.

Scenario 3: One Sponsor Plus Multiple Investigators

Dr. Zhivago holds an IND and is Principal Investigator of the protocol under that IND at his own institution.

Dr. Frankenstein and Dr. No, two researchers at separate academic research centers, are Principal Investigators of the protocol under Dr. Zhivago’s IND at their respective institutions.

EXERCISE: SELECTING AND INFORMING INVESTIGATORS / SCENARIO 1

A. Dr. Jekyll must be qualified to conduct the study.

B. Dr. Jekyll must have sufficient information to conduct the study.

Sponsor responsibilities include:

- Select investigators qualified by training and experience
- Obtain Form FDA 1572 and financial disclosure information
- Give each participating investigator an investigator brochure, except individual Sponsor-Investigator
- Provide investigators with necessary information to conduct study

What processes and procedures can Dr. Jekyll establish to make sure her Sponsor obligations are met?

A.

B.

What documentation does Dr. Jekyll need to prove that she has fulfilled her Sponsor obligations?

A.

B.

EXERCISE: SELECTING AND INFORMING INVESTIGATORS / SCENARIO 2

A. Dr. Moreau must be qualified to conduct the study.

B. Dr. Watson must provide Dr. Moreau with sufficient information to conduct the study.

Sponsor responsibilities include:

- Select investigators qualified by training and experience
- Obtain Form FDA 1572 and financial disclosure information
- Give each participating investigator an investigator brochure, except individual Sponsor-Investigator
- Provide investigators with necessary information to conduct study

What processes and procedures can Dr. Watson have in place to make sure her Sponsor obligations are met?

A.

B.

What documentation does Dr. Watson need to prove that she has fulfilled her Sponsor obligations?

A.

B.

EXERCISE: SELECTING AND INFORMING INVESTIGATORS / SCENARIO 3

A. Drs. Zhivago, Frankenstein, and No must be qualified to conduct the study.

B. Dr. Zhivago must provide Investigators with sufficient information to conduct the study.

Sponsor responsibilities include:

- Select investigators qualified by training and experience
- Obtain Form FDA 1572 and financial disclosure information
- Give each participating investigator an investigator brochure, except individual Sponsor-Investigator
- Provide investigators with necessary information to conduct study

What processes and procedures can Dr. Zhivago have in place to make sure his Sponsor obligations are met?

A.

B.

What documentation does Dr. Zhivago need to prove that he has fulfilled his Sponsor obligations?

A.

B.