

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: MONITORING / SCENARIO 1

A. Dr. Jekyll must arrange protocol monitoring.

B. The monitor discovers that two participants received an incorrect dose of study drug.

Sponsor responsibilities include:

- Select monitors qualified by training and experience
- Monitor the progress of all clinical investigations under the IND
- Ensure investigation is conducted in accordance with protocol, investigator statement (1572), and regulations
- Secure compliance or discontinue investigator participation if non-compliance is identified

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: MONITORING / SCENARIO 2

A. Dr. Watson must arrange protocol monitoring.

B. The monitor discovers that two participants received an incorrect dose of study drug.

Sponsor responsibilities include:

- Select monitors qualified by training and experience
- Monitor the progress of all clinical investigations under the IND
- Ensure investigation is conducted in accordance with protocol, investigator statement (1572), and regulations
- Secure compliance or discontinue investigator participation if non-compliance is identified

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: MONITORING / SCENARIO 3

A. Dr. Zhivago must arrange protocol monitoring.

B. The monitor discovers that two participants at Dr. No's site received an incorrect dose of study drug.

Sponsor responsibilities include:

- Select monitors qualified by training and experience
- Monitor the progress of all clinical investigations under the IND
- Ensure investigation is conducted in accordance with protocol, investigator statement (1572), and regulations
- Secure compliance or discontinue investigator participation if non-compliance is identified

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.