

## Sponsor-Investigator IND Scenarios

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### *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.

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### *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.

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### *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: INVESTIGATIONAL PRODUCT ACCOUNTABILITY / SCENARIO 1

Mr. Hyde, a participant in a study involving long-term use of an investigational oral drug, has a study visit with Dr. Jekyll.

A. Mr. Hyde says, "I think I took most of my medicine on time, but I dropped a couple of pills on the floor last week and threw them away."

B. Mr. Hyde says, "I'm spending the winter in Arizona. Can you send my medicine to my doctor there?"

Sponsor responsibilities include:

- Provide investigational product only to participating investigators
- Assure return of unused investigational product, or authorize alternative disposition
- Maintain records of product receipt, shipment, other disposition

*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: INVESTIGATIONAL PRODUCT ACCOUNTABILITY / SCENARIO 2

Holmes Pharmaceuticals manufactures and provides the drug used under Dr. Watson's IND. Dr. Watson is on the phone with a representative from the company.

A. Holmes says, "Are you sure you sent that expired batch of drug back to us? I thought your pharmacy destroyed it on site."

B. Holmes says, "Dr. Moreau is conducting a study for us, and his drug shipment got delayed. Can you transfer the drug from your stock to Dr. Moreau's other study for his patient tomorrow?"

Sponsor responsibilities include:

- Provide investigational product only to participating investigators
- Assure return of unused investigational product, or authorize alternative disposition
- Maintain records of product receipt, shipment, other disposition

*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: INVESTIGATIONAL PRODUCT ACCOUNTABILITY / SCENARIO 3

Dr. Zhivago holds a weekly teleconference with the Investigators conducting studies under his IND.

A. Dr. Frankenstein says, “Most of our sponsors have our pharmacy destroy leftover study drug on-site. Do we really have to send it back to you?”

B. Dr. No says, “Our pharmacy got fifty drug shipments in the last three days, and they’re losing track of everything! Can you help them figure it out?”

Sponsor responsibilities include:

- Provide investigational product only to participating investigators
- Assure return of unused investigational product, or authorize alternative disposition
- Maintain records of product receipt, shipment, other disposition

*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.