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: REPORTING IND ACTIVITY / SCENARIO 1

Dr. Jekyll's IND has been in effect for one year. Interim data show an unexpected number of adverse events in one cohort of study participants, so she has determined that dosage of study drug for this cohort must be decreased.

Sponsor responsibilities include:

- Report to FDA on all protocols and study sites under IND
- Submit protocol changes that significantly affect subject safety, scope of investigation, or scientific quality of the study
- Submit new protocols or new investigators
- Submit IND safety reports and other safety information reflecting all use of investigational product
- Submit annual reports including progress of investigations at all study sites

What processes and procedures can Dr. Jekyll establish to make sure her Sponsor obligations are met?
What documentation does Dr. Jekyll need to prove that she has fulfilled her Sponsor obligations?

EXERCISE: REPORTING IND ACTIVITY / SCENARIO 2

Dr. Watson's IND has been in effect for one year. Interim data show an unexpected number of adverse events in one cohort of study participants, so she has determined that dosage of study drug for this cohort must be decreased.

Sponsor responsibilities include:

- Report to FDA on all protocols and study sites under IND
- Submit protocol changes that significantly affect subject safety, scope of investigation, or scientific quality of the study
- Submit new protocols or new investigators
- Submit IND safety reports and other safety information reflecting all use of investigational product
- Submit annual reports including progress of investigations at all study sites

What processes and procedures can Dr. Watson have in place to make sure her Sponsor obligations are met?
What documentation does Dr. Watson need to prove that she has fulfilled her Sponsor obligations?

EXERCISE: REPORTING IND ACTIVITY / SCENARIO 3

Dr. Zhivago's IND has been in effect for one year. Interim data show an unexpected number of adverse events in one cohort of study participants, so he has determined that dosage of study drug for this cohort must be decreased.

Sponsor responsibilities include:

- Report to FDA on all protocols and study sites under IND
- Submit protocol changes that significantly affect subject safety, scope of investigation, or scientific quality of the study
- Submit new protocols or new investigators
- Submit IND safety reports and other safety information reflecting all use of investigational product
- Submit annual reports including progress of investigations at all study sites

What processes and procedures can Dr. Zhivago have in place to make sure his Sponsor obligations are met?
What documentation does Dr. Zhivago need to prove that he has fulfilled his Sponsor obligations?