Version 1.0 of a protocol is released and will be conducted in both the U.S. and South Africa. IRBs at U.S. sites deem the study to be of minimal risk, whereas your IRB in South Africa determines the protocol to be greater than minimal risk.

Recent updates to U.S. federal policy have resulted in changes that require a "Key Element" summary to be added to the beginning of all informed consent forms, to be in effect for all new studies next year. Your site elects to implement the change now for all current, ongoing protocols.

An investigator performs prospective medical chart reviews to collect medical data on premature infants in a neonatal intensive care unit (NICU) for a research registry. An infant, about whom the investigator is collecting medical data for the registry, dies as the result of an infection that commonly occurs in the NICU setting.

The fifth subject enrolled in a phase II, open-label, uncontrolled clinical study evaluating the safety and efficacy of a new oral agent administered daily develops severe hepatic failure complicated by encephalopathy one month after starting the oral agent. The known risk profile of the new oral agent prior to this event included mild elevation of serum liver enzymes in 10% of subjects receiving the agent during previous clinical studies, but there was no other history of subjects developing clinically significant liver disease. The IRB-approved protocol and informed consent document for the study identifies mild liver injury as a risk of the research. The investigators identify no other etiology for the liver failure in this subject and attribute it to the study agent.

An investigator conducting behavioral research collects individually identifiable sensitive information about illicit drug use and other illegal behaviors. Data are stored on a laptop computer without encryption, and the laptop computer is stolen from the investigator's car on the way home from work.

A site maintains a stock of infrequently used topical medications for use in a clinical trial. During a study visit, site staff go to retrieve the medication for a participant but see that the stock is now expired, and no unexpired drug is available.

A clinical research site is notified of an institutional data breach that resulted in the release of some medical patient's names, medical record numbers, and other information on the internet.

A participant engaged in a vaccine study becomes incarcerated during the conduct of the study. The protocol was not approved to enroll prisoners.

A dear participant letter is being used in this study and needs to be approved by the IRB.

A multi-arm clinical trial evaluating two antiretroviral (ARV)-based approaches for preventing sexual transmission of HIV in women (a vaginal gel or daily use of one of two different ARV tablets) elects to drop one of the oral tablets from the study due to failure to demonstrate efficacy.