

Informed Consent Form Role Play Activity

Instructions:

Participants will observe two of their co-participants performing a skit. The remainder of the participants will raise a red flag every time they hear something that is an issue or a risk. Following the skit, they will review the red flags as a large group.

Scenario:

This is a conversation which takes place between the CRA, Imani and the site's Study Coordinator, Lesedi during an Interim Monitoring Visit on 16 July 2019.

Imani: Lesedi would you have a few minutes to discuss a few observations I have made while reviewing some informed consents?

Lesedi: Sure, let's chat.

Imani: I noticed the participant signed Version 1 of the consent on 12 July 2019, two days after Screening procedures were completed.

Lesedi: Ok.... anything else?

Imani: Also, a protocol amendment was issued 04 June 2019, however I see no evidence of an Ethics Committee submission taking place with a revised Version 2 consent seeking Ethics Committee approval capturing the added lab draw at Visit 5.

Lesedi: That's interesting??

Imani: I also reviewed a consent that appears to have been missing a participant's signature date. A date was filled in; however, the penmanship does not appear to be the same as the participant's penmanship.

Lesedi: Oh, sometimes the participants forget to date their consent, so we do that for them.

Imani: Hmm, one other consent I reviewed at my last monitoring visit showed the Principal Investigator failed to sign and date the consent on the same day as the participant was consented. As you know, this is a Sponsor requirement. Today, I reviewed that same consent and noted the Principal Investigator signed the consent and dated it, 12 July 2019.

Lesedi: Well, wasn't that the day the participant was consented?

Imani: Hmm.....