

# Safety /Safety Oversight Role Play Activity Answer Key

Activity Title: The Case of the Slip and Fall

## Activity Guiding Questions Answer Key:

1. Does she need to report this incident at her clinic? If so, why, when does she needs to report this and to whom?

Yes, she needs to report the incident to site staff at her next research visit.

2. If Charlene does not report this event herself, how would the study team learn of this event?

At the next study visit, the study team should ask Charlene if there have been any changes to her baseline.

3. Would this be considered an Adverse Event or Serious Adverse Event?

This is a clear Serious Adverse Event because it meets the criteria for a Serious Adverse Event (Congenital, Hospitalization, Incapacity, Life threatening, Death, other- CHILDO) the participant was hospitalized as a result of the incident and needed surgery as well.

4. Does this need to be reported in an expedited fashion?

They know it has to be reported as a Serious Adverse Event, because this was answer in Question in #3. However, we would need more protocol specific information about expedited reporting requirements.

5. Does it this needs to be entered in the DAERS?

Not without knowing more protocol specific information.

