

# Safety /Safety Oversight Role Play Activity Guiding Questions

Title: The Case of the Slip and Fall

## Activity Guiding Questions:

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

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

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

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

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5. Does this need to be entered in the DAIDS Adverse Events Reporting System (DAERS)?

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