

# Safety /Safety Oversight Case Study Activity Answer Key

Activity Title: The Case of The ABC Participant

## Activity Guiding Questions Answer Key:

You are the study nurse:

1. What further information would you ask the participant?

Dates of hospitalisation, Areas of physical assault, Treatment/Medication received, Copies of medical records.

2. What Forms you are required to complete?

AE Case Report Form, Con Med Case Report Form, Sponsor required SAE Form- With DAIDS complete required info on DAERS.

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

3. Who and within what timeline would submit the forms to? To whom and within what timeframe would you submit the required forms?

Sponsor/protocol team within stipulated timelines, IRB/EC as per local requirements

4. Upon further probing, the participant disclosed that the reason for the assault was due to the fact that she had joined the study and was coming to the clinic. What are your follow-up actions from this report?

This should be reported as a social harm and site should completing reporting as per protocol and local IRB/EC requirements.

