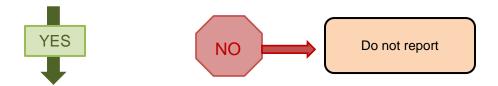
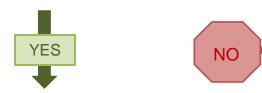
Was the event related to the research?

- Reasonable possibility that the event was caused by <u>research procedures</u>
- Includes events that are definitely or possibly related to the <u>research procedures</u>



Was the event unanticipated ?

- Unforeseen given the nature of the research and subject population
- Not described in the protocol, consent form or other information given to participants



Did the event involve risks to subjects or others?

- Includes adverse events, protocol deviations, other problems or events
- May involve physical, psychological, social, legal or economic harms

