

# Essential Element 6: Quiz

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1. The process of obtaining participants' informed consent:  
(Check all that apply.)

- must be in the language of the investigators of the study
- is the primary responsibility of the investigators and their institutions
- must explain benefits and risks of the trial and consequences of participating in the local language understood by the target population
- is no different for studies that target young children, adults with severe mental or behavioural disorders, or persons who are unfamiliar with medical concepts and technology than for studies that do not include those populations

2. The Protocol should include the following information about informed consent:  
(Check all that apply)

- whether informed consent can be waived, including the justification or rationale for any waiver
- how consent will be documented from illiterate populations and/or individuals unable of giving informed consent, if applicable
- whether local ethics review board or Community Advisory Board approval of consent document and/or consent process is required
- whether secondary use of biological specimens is a possibility and how consent will be sought for secondary use

3. Cultural considerations—such as the role of family leaders, tribal leaders, and local standards for signatures—need to be taken into account in giving and obtaining consent.

- True
- False

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