Module 4: Principles applied in the Planning and Design of the Study

Case Scenario:

A global health research network is designing a decentralized, multicentre study to evaluate the efficacy of a novel antibiotic combination for carbapenem-resistant urinary tract infections in young women in peri-urban areas of Latin America, Asia, and Africa. An electronic platform is planned for informed consent and home-based symptom monitoring, given barriers to accessing health facilities.

During the protocol review, one of the local ethics committees noted that the proposed electronic consent did not comply with the country's regulations and that the consent document lacked information on potential gastrointestinal effects, which had been observed in previous studies. Furthermore, it was noted that most potential participants were economically vulnerable, and that there were linguistic variations.

The research team, together with the sponsor, decided to translate all materials into local languages, incorporate audiovisual tools, and establish an optional in-person consent module with interpreters. They also updated the protocol and investigator's brochure to reflect the side effects, and redesigned the compensation plan to avoid coercive incentives.

Questions:

1. **What ethical principle of clinical trial design is reinforced by adapting informed consent to local languages and cultures?**

   A) Operational efficiency
   B) Justice and respect for people
   C) Scientific justification
   D) Minimization of logistics costs

2. **What is an appropriate action from the perspective of ethical and scientific planning of the study?**

   A) Implement electronic consent without ethical approval to speed up processing times
   B) Design the protocol without considering previous gastrointestinal risks
   C) Update the investigator's brochure and protocol with the new data before submitting them to the IRB/IEC
   D) Accept that participants may not understand the consent if they have already signed

3. **What measure prevents compensation from becoming a coercive incentive for vulnerable populations?**

A) Establish a fair, proportional and clearly explained compensation system
B) Offer different payment amounts for different groups
C) Condition compensation on full compliance with the protocol
D) Avoid reporting compensation in the consent to avoid influencing

Answers and Feedback:

1. **What ethical principle of clinical trial design is reinforced by adapting informed consent to local languages and cultures?**

   A) Operational efficiency
   B) Justice and respect for people
   C) Scientific justification
   D) Minimization of logistics costs

Feedback: Adapting consent to the cultural and linguistic conditions of participants guarantees the principle of justice and respect for autonomy, aligned with the Belmont principles and ICH GCP E6(R3), especially when working with vulnerable populations.

2. **What is an appropriate action from the perspective of ethical and scientific planning of the study?**

   A) Implement electronic consent without ethical approval to speed up processing times
   B) Design the protocol without considering previous gastrointestinal risks
   C) Update the investigator's brochure and protocol with the new data before submitting them to the IRB/IEC
   D) Accept that participants may not understand the consent if they have already signed

Feedback: According to ICH E6(R3), planning should include ongoing ethical assessment, where the incorporation of new evidence (such as adverse events) into the protocol and investigator's brochure is mandatory and must be assessed by the ethics committee before starting or continuing the study.

3. **What measure prevents compensation from becoming a coercive incentive for vulnerable populations??**

   A) Establish a fair, proportional and clearly explained compensation system
   B) Offer different payment amounts for different groups
   C) Condition compensation on full compliance with the protocol
   D) Avoid reporting compensation in the consent to avoid influencing

Feedback: ICH GCP E6(R3) emphasizes that compensation should be ethical and non-coercive, especially for vulnerable populations. It should reflect time, transportation, or inconvenience, without constituting an incentive that overrides the participant's free choice.