Module 7: Principles applied in Conclusion, Closure and Post Study

Case Scenario:

> After completing a cancer trial, Dr. Kumar discovers that the investigational treatment significantly improves survival outcomes. The IRB/IEC requests a plan to provide ongoing access to the treatment for participants who benefited. The sponsor agrees and works with local health authorities to make the drug available post-trial. Meanwhile, Dr. Kumar ensures that participants are notified of the final study results and potential long-term implications. The ethics committee reviews the final results and confirms that participant rights and safety were respected.

Questions:

1. **Why is it important to communicate results to participants after a study ends?**

   A) To boost the site's reputation
   B) To ensure transparency and respect for participant rights
   C) To recruit them for the next study
   D) To satisfy marketing requirements

2. **What should be done if a treatment proves beneficial during a clinical trial?**

   A) Evaluate options for post-trial access in collaboration with IRB/IEC and local authorities
   B) Store it for future studies
   C) Offer it only to new patients
   D) Reassign it to another sponsor

3. **What is one key post-study role of the IRB/IEC?**

   A) Designing the next trial
   B) Approving study branding
   C) Selling the data to journals
   D) Reviewing final outcomes and ensuring participants' long-term safety and care

Answers and Feedback:

1. **Why is it important to communicate results to participants after a study ends?**

   A) To boost the site's reputation
   B) To ensure transparency and respect for participant rights
   C) To recruit them for the next study
   D) To satisfy marketing requirements

Feedback: According to ICH E6(R3) and international ethical principles (such as the Declaration of Helsinki), participants have the right to know the results of the study in which they participated. This communication demonstrates respect, reinforces transparency, and fosters trust in clinical research.

2. **What should be done if a treatment proves beneficial during a clinical trial?**

   A) Evaluate options for post-trial access in collaboration with IRB/IEC and local authorities
   B) Store it for future studies
   C) Offer it only to new patients
   D) Reassign it to another sponsor

Feedback: Post-trial access to beneficial treatments is part of the ethical responsibility of researchers and sponsors. ICH E6(R3) promotes planning for this access in conjunction with ethics committees and health authorities, prioritizing the well-being and continuity of care of participants.

3. **What is one key post-study role of the IRB/IEC?**

   A) Designing the next trial
   B) Approving study branding
   C) Selling the data to journals
   D) Reviewing final outcomes and ensuring participants' long-term safety and care

Feedback: The role of the IRB/IEC does not end with the completion of recruitment; it continues to ensure that the rights and safety of participants are maintained at all times. This includes reviewing final results and monitoring long-term implications, as recommended by ICH E6(R3) in its ongoing approach to subject protection.