Essential Element 8: Quiz

1. A study set up to test the effectiveness of a drug for heart disease found unexpectedly that some study participants have other significant health concerns. What are these findings called?
   - O Individual Research Results
   - O Incidental Findings
   - O Return of Results
   - O Therapeutic Misconception

2. The study protocol for the return of research results might include how the following will be handled:
   (Check all that apply.)
   - O Disclosure of general research results
   - O Disclosure of individual research results
   - O Disclosure of incidental findings
   - O Options for participants to opt-in or opt-out of receiving research results

3. Researchers need to clarify to study participants that the participants’ individual care and treatment is not the primary goal of the research and need to establish clear criteria for which results to return to participants.
   - O True
   - O False

4. Clearly spelling out the scope of obligation for an investigator to return results to study participants can help manage the expectations of participants and the liability of investigators.
   - O True
   - O False

5. A study found that an existing medication can be used to reduce the health threat of Lassa Fever. This is an example of what kind of returnable results?
   (Choose the best answer.)
   - O Analytically valid
   - O Clinically significant
   - O Medically actionable
   - O Permitted to be returned

6. Which of the following should be considered in a proposal about how to handle individual research results and incidental findings?
   - O a) Degree to which participants have an opportunity to state their preferences about the information they want to learn
   - O b) Circumstances under which an ethics board overseeing the research can override participants’ decision to opt-out of learning results
   - O c) Financial costs associated with identifying, confirming and managing research findings
   - O d) All of the above
   - O e) A and B only
7. A good plan for returning information to participants will discuss how to deal with general research results, individual research results, and incidental findings all at once since there is little difference in how to handle these.

   ○ □ True
   ○ □ False

8. Which of the following is/are an example/s of incidental finding?
   ○ □ a) A kidney tumor detected through a research MRI that was performed for the analysis of an unrelated body part.
   ○ □ b) Results from whole-genome sequencing that indicate a high risk of cancer for some participants.
   ○ □ c) A positive anemia test conducted in a CLIA-certified laboratory during a screening test.
   ○ □ d) All of the above.
   ○ □ e) A and B only