

***BRIDGE Patient to Investigator Training Module 6***  
***Key Types of Study Documents Review Questions and Answer Key***

**Questions:**

- 1. What is a research proposal? (choose all that make sense)**
  - a. A research proposal is a summary of a research project that is written to explain the research idea and how the research is to be done.
  - b. It can be used to request funding to carry out the research and to get other researchers to participate.
  - c. Research proposals can be written in response to a request or opportunity from a group that funds research like NIH or PCORI or a Foundation.
  - d. All of the above
  
- 2. A study protocol is a document that lays out the exact details of what the research team plans to do in the study.**
  - a. True
  - b. False
  
- 3. An informed consent document outlines what people who are thinking about joining a study are agreeing to if they decide to join the study.**
  - a. True
  - b. False
  
- 4. What is a Statistical Analysis Plan (SAP) and what does it include?**
  - a. A Statistical Analysis Plan may be a separate document or this information may be included in the protocol.
  - b. The plan describes how the data will be analyzed, including the tables used to describe the results of the study.
  - c. It may include a description of the types of tests or statistical techniques to be used during analysis of the study information.
  - d. All of the above
  
- 5. You are expected to know statistical methods and techniques.**
  - a. True
  - b. False
  
- 6. When reviewing patient-facing materials such as recruitment materials like emails, flyers, posters or an informed consent document, it is important to make sure the language is clear and understandable.**
  - a. True
  - b. False

## **Answers**

1. **d**

**Explanation:** All of the answers listed are correct so “all of the above” is the best answer option. A research proposal is written to explain a research idea and how that research is to be done; it can be used to request funding; and research proposals can be written in response to a request or an opportunity from a group that funds research.

2. **a**

**Explanation:** True is the correct answer, a study protocol is a document that lays out the exact details of what the research team plans to do in the study.

3. **a**

**Explanation:** True is the correct answer, an informed consent document outlines what people who are thinking about joining a study are agreeing to if they decide to join the study.

4. **d**

**Explanation:** All of the answers listed are correct so “all of the above” is the best answer option. A Statistical Analysis Plan may be a separate document or this information may be included in the protocol; it describes how the data will be analyzed, including the tables used to describe the results of the study; and It may include a description of the types of tests or statistical techniques to be used during analysis of the study information.

5. **b**

**Explanation:** False is the correct answer. You are not expected to know statistical methods and techniques.

6. **a**

**Explanation:** True is correct answer. When reviewing patient-facing materials such as recruitment materials like emails, flyers, posters or an informed consent document, it is important to make sure the language is clear and understandable.