



MODULE 6

KEY TYPES OF STUDY DOCUMENTS

Overview of Module 6: Key Types of Study Documents

In this section, we will go over the types of study documents you can expect to review:

- **Research Proposals**
- **Study Protocols**
- **Statistical Analysis Plan**
- **Informed Consent Document**
- **Patient-Facing Materials**

Estimated Time Commitment for Module 6: 15-25 minutes

Feel free to take breaks along the way – you can do this at your own pace!



Key Terms Used in this Module

- You will hear a lot of **new terms** during this module that you might not know
- We do **not expect you to know what these terms mean right away or memorize them** – just to familiarize yourself with the words
- Here is a **link to the key terms** used in this module that you can reference as you go through – click [here](#)

Key Types of Study Documents

- As an active member of the research team you will be asked to review different types of documents
- Your feedback on these documents is important to help make sure the patient/caregiver point of view is taken into account
- These slides will go through some of the key documents and what you might want to look for when reviewing



Research Proposal

What is a research proposal?

- 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.
- It can be used to request funding to carry out the research and to get other researchers to participate.
- Research proposals can be written in response to a request or opportunity from a group that funds research like the National Institute of Health (NIH) or the Patient-Centered Outcomes Research Institute (PCORI) or a Foundation.



Research Proposal continued...

What are some typical sections in a research proposal?

Abstract	This is a short summary of the research that highlights why the study needs to be done, how it will be done, who and how many will be invited to the study and how the information will be analyzed.
Introduction & Background	This section states why the study is being done, what has been done before and how this study will answer an important problem or gap in information.
Description of Proposed Research	This section describes who will be invited to do the study, what will be done during the study such as types of information collected, tests to be done, how many visits and/or surveys are required and how long the study lasts.
Personnel	This section outlines the people involved in doing the research and their skills.
Primary and Secondary Outcomes	Outcomes describe what is being measured (<i>for example: change in lung function; improved quality of life; improved exercise ability</i>).
Budget & Budget Justification	This section details what the research study will cost and why these costs are needed.

Research Proposal continued...

What should you look for when reviewing a research proposal?

- Is the research being described **important to the people being studied**?
- Is there **another question/issue that is important to the people** that the researchers should ask/study?
- Is what is being **measured (the outcomes) important to the people** being studied?
- Is what they are asking of people who join the study **realistic**?
- Is there **too much burden** placed on people who join the study?
- What are the **benefits** of this study to people who join the study?
- Are there any unnecessary **risks**?
- **Who** is being included in the study?



Study Protocol

What is a Study Protocol?

- A study protocol is a document that lays out the exact details of what the research team plans to do in the study.
- It is used to guide the study team throughout the study.
- This document is sent to an institutional review board (IRB) for approval before the study can begin.

What does a study protocol include?

- Question(s) to be answered
- Study Objectives—what exactly is to be accomplished
- Population to be studied and how many people will be included
- Risks and/or Benefits to participants
- What information will be collected and exactly how it is collected
- How the information will be analyzed (Statistical Analysis Plan)
- Step by step actions to complete the research



Study Protocol continued...

What should you look for when reviewing a research protocol?

- Is too much **burden** being placed on the people being studied (a lot of travel, too many calls, etc.)
- Overall is what is being **asked of participants** realistic?
- Are there any **unneeded risks**?
- Are people being **paid for their time and efforts**?
- Does the research **make sense** overall?



Statistical Analysis Plan

What is a Statistical Analysis Plan (SAP) and what does it include?

- A Statistical Analysis Plan may be a separate document, or this information may be included in the protocol.
- The plan describes how the data will be analyzed, including the tables used to describe the results of the study.
- It may include a description of the types of tests or statistical techniques to be used during analysis of the study information.



Statistical Analysis Plan continued...



What would you do to review a statistical analysis plan?

- You are not expected to know about the statistical methods or techniques
- However, you can look at the plan to see:
 - Is all of the information that is collected used for the analysis?
 - *For example, does the protocol list collecting the person's occupation but is that information never used in the analysis?*
 - *Or does the protocol say a blood test will be done but the results of that blood test are not in the analysis plan?*
 - Is the information or data in the analysis the same as what is collected
 - *For example, does the Statistical Analysis Plan (SAP) say they will compare the spirometry (lung function test) at 3,6 and 12 months but the protocol only says they will do lung function tests at 3 and 12 months.*

Informed Consent Document

What is an informed consent document?

- It is a document that outlines what people who are thinking about joining a study are agreeing to if they decide to join the study.
- In most cases research participants are asked to read and after asking any questions, to sign the informed consent document, but in some cases, consent can be given verbally.
- It is a voluntary agreement – it is not a contract. Someone can change their mind about participating at any time.

What does an informed consent document include?

- Overview of the study
- Information about what a study participant will do as part of joining the study
- Risks and/or benefits of joining the study
- Information on how your privacy will be protected
- The person's rights during the study including stopping at any time for any reason



Informed Consent Document continued...



What should you look for when reviewing an informed consent document?

- Is the language in the informed consent document **clear**? Do you understand what it is saying? Is there too much medical language or jargon?
- Are all the possible risks and benefits to the participant included?
- Is it clear that joining the study is voluntary?
- Is it clear that a participant can stop at any time for any reason?
- Is there a number for a participant to call if they are having issues?

Patient-Facing Materials

What are patient-facing materials?

- These are any materials that participants in a study will see or hear
- They include things like:
 - *Recruitment materials such as emails, flyers, posters*
 - *Surveys used in the study*
 - *Instructional documents*
 - *Informed consent document*
 - *Phone scripts*
- These types of documents are important and need to use plain language and be very clear





What should you look for when reviewing patient-facing materials?

- Is the language in these documents clear? Do you understand what it is saying? Is there too much medical language or jargon?
- Is it clear what is being asked of people who join the study?
- Are the details the same across the different recruitment documents (emails, flyers, posters)?
- If you are reviewing a survey, are the questions clear? Or is what is being asked confusing?

MODULE 6: REVIEW QUESTIONS

- The next few slides have some questions to help you review and remember what we have presented in this Module.
- This is not a graded test and is meant to only help you retain the information from this Module. There is an answer key at the end.
- Here is a link to the key terms that might help as you go through the review questions: click [here](#)
- If you have any questions, please email BRIDGE@copdfoundation.org



MODULE 6: REVIEW 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

MODULE 6: REVIEW QUESTIONS CONTINUED...

- 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

MODULE 6: REVIEW QUESTIONS ANSWER KEY

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.

MODULE 6: REVIEW QUESTIONS ANSWER KEY CONTINUED...

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.

LINKS TO KEY RESOURCES FOR MODULE 6

Below is a table with links to key resources and information that you might find useful

Takeaway Documents	<ul style="list-style-type: none">• Glossary of Key Terms: click here• Module 6 Review Questions with Answers and Explanations: click here• Module 6 Summary Document: click here
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Congratulations! You have completed Module 6!

When you are ready, please go on to ***Module 7 – Protections for Research Participants***

You don't have to do this right away – you can do it when you have time.

