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BRIDGE Patient to Investigator Training Module 6
Key Types of Study Documents Summary Document

As part of research study teams, patient partners may be asked to review different types of documents. Your feedback is essential to make sure the patient/caregiver perspective is present.

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, or 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.

Sections of a Research Proposal:

- Abstract
- Introduction and Background
- Description of Proposed Research
- Personnel
- Primary and Secondary Outcomes
- Budget and Budget Justification

What to 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: 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 and is sent to an institutional review board (IRB) for approval before the study can begin.

A Study Protocol Includes:

- 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

What to look for when reviewing a study 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 (SAP):

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.

You are not expected to know about the statistical methods or techniques.

What to look for when reviewing a statistical analysis plan:

- **Is all of the information that is collected used for the analysis?**
  - *For example, does the protocol list collecting the person's occupation but that information is 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:

An informed consent document 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.

An Informed Consent Includes:

- 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

What to look for when reviewing an informed consent:

- 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: These are any materials that participants in a study will see - like recruitment materials (emails, flyers or posters), surveys used in the study, instructional documents and informed consent documents, or hear - like phone scripts. These types of materials are important and need to use plain language and be very clear.

What to 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?