

BRIDGE Patient to Investigator Training Module 6 Key Types of Study Documents Key Terms and Definitions

Abstract: An abstract 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.

Funder: A funder is a person or organization that provides money for a particular purpose.

Informed Consent Document: A document that outlines what people who are thinking about joining a study are agreeing to if they decide to join the study.

Institutional Review Board (IRB): A group that follows federal regulations, state laws, and institutional policy to review, monitor, and approve research in order to protect the ethical rights and privacy of the participants involved.

Patient-Facing Materials: These are any materials that participants in a study will see, as in recruitment materials such as emails, flyers, posters, surveys used in the study, Instructional documents, etc.

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.

Statistical Analysis Plan (SAP): A statistical analysis plan may be a separate document or 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.

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.