

BRIDGE Patient to Investigator Training Module 4
Designing, Doing and Sharing a Research Study Key Terms and Definitions

Consent Participants: To "consent participants" means to tell the patients about the potential benefits of a study without promising too much, the potential risks of participating in the study in language that is clear but not frightening, and the rights of the patient in understandable, clear terms.

Exclusion Criteria: Exclusion criteria are those characteristics that disqualify prospective participants from inclusion in a study.

Inclusion Criteria: Inclusion criteria are characteristics that the prospective participants must have if they are to be included in a 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.

Literature Review: A literature review is a survey of scholarly sources (such as books, journal articles, and theses) to discover what other studies have been completed on the topic and what is already known on the topic.

Primary Outcome: The primary outcome is the main measure of the study on which the statistics is built – ensuring enough participants to reasonably detect an important difference.

Qualitative Data: Data which is based on opinions, preferences or observations; what is told or said via interviews or open-ended questions.

Quantitative Data: Data which can be measured and given a numeric value and shown in tables and graphs.

Request for Proposal (RFP): A request for proposal is a document that describes a project's needs and asks for proposed solutions from qualified vendors.

Secondary Outcome(s): Secondary outcomes are other outcomes that matter and will be measured – some may not occur frequently enough to determine a difference (statistically significant) but researchers should measure, e.g., in a study that targets preventing going to hospital (primary) other outcomes like death, patient satisfaction, cost might also be measured.

Statistical Analysis: Statistical analysis is the technique used to make sense of, and draw some inferences from, data collected.