Medical Manuscript Preparation

Study Design and Ethics

Abstract: An abstract is a brief summary of a research study, usually around 250-300 words, that provides an overview of the study's objective, methodology, results, and conclusion. It is often used to help readers quickly understand the main points of the study and decide whether to read the full paper. Related terms: Summary, synopsis, overview.

Accountability: Accountability in research refers to the responsibility of researchers to ensure that their studies are conducted in an ethical and responsible manner. This includes obtaining informed consent from participants, protecting their privacy and confidentiality, and avoiding any harm or exploitation. Related terms: Responsibility, ethics, compliance.

Adverse Event: An adverse event is any unwanted or unexpected consequence of a medical treatment or intervention, such as a side effect or complication. In research studies, adverse events must be carefully monitored and reported to ensure the safety of participants. Related terms: Side effect, complication, harm.

Alternative Hypothesis: The alternative hypothesis is a statistical hypothesis that suggests that there is a significant difference or relationship between variables. It is often denoted as H1 and is used in conjunction with the null hypothesis to test the significance of research findings. Related terms: Null hypothesis, statistical significance, hypothesis testing.

Analysis of Variance (ANOVA): ANOVA is a statistical technique used to compare the means of two or more groups to determine if there are any significant differences between them. It is commonly used in research studies to analyze the effects of different treatments or interventions. Related terms: Statistical analysis, hypothesis testing, mean comparison.

Animal Research: Animal research involves the use of animals in scientific studies to advance our understanding of human disease and develop new treatments. It is heavily regulated by laws and guidelines to ensure that animals are treated humanely and with respect. Related terms: Animal welfare, animal testing, research ethics.

Anonymity: Anonymity in research refers to the protection of participants' identities and personal information to prevent any potential harm or exploitation. Researchers must take steps to ensure that participants' data is kept confidential and anonymous. Related terms: Confidentiality, privacy, data protection.

Assent: Assent is the agreement of a participant to take part in a research study, usually obtained from children or individuals who are not capable of providing informed consent. It is an important aspect of research ethics and must be obtained in conjunction with parental or guardian consent. Related terms: Informed consent, consent, research ethics.

Audit Trail: An audit trail is a record of all changes made to research data, including any edits, corrections, or

updates. It is an essential tool for ensuring the integrity and accuracy of research findings. Related terms: Data management, data quality, research integrity.

Bayesian Analysis: Bayesian analysis is a statistical technique that uses Bayes' theorem to update the probability of a hypothesis based on new data or evidence. It is commonly used in research studies to analyze complex data and make informed decisions. Related terms: Statistical analysis, probability, hypothesis testing.

Bias: Bias in research refers to any systematic error or distortion that can affect the validity and reliability of research findings. It can occur due to various factors, such as sampling errors, measurement errors, or researcher biases. Related terms: Error, distortion, validity.

Blinded Study: A blinded study is a research design in which participants, researchers, or outcome assessors are unaware of the treatment or intervention being administered. This helps to reduce bias and ensure the objectivity of research findings. Related terms: Double-blinded, single-blinded, masked.

Case-Control Study: A case-control study is a research design that compares individuals with a specific outcome or disease (cases) with those without the outcome or disease (controls). It is commonly used to identify risk factors and causes of diseases. Related terms: Observational study, cohort study, case series.

Case Series: A case series is a research design that involves the collection and analysis of data from a series of individuals with a specific condition or disease. It is often used to describe the characteristics and outcomes of a particular disease or treatment. Related terms: Case report, case study, descriptive study.

Causal Inference: Causal inference is the process of drawing conclusions about the causal relationships between variables based on research findings. It involves the use of statistical techniques and research designs to establish cause-and-effect relationships. Related terms: Causality, correlation, statistical analysis.

Clinical Significance: Clinical significance refers to the practical importance or relevance of research findings in a clinical or real-world setting. It is often evaluated in terms of the magnitude of the effect size, the number needed to treat, and the potential impact on patient outcomes. Related terms: Practical significance, effect size, number needed to treat.

Clinical Trial: A clinical trial is a research study that evaluates the safety and efficacy of a new treatment, intervention, or product in human participants. It is a crucial step in the development of new medical treatments and involves several phases, including Phase I, II, III, and IV trials. Related terms: Randomized controlled trial, phases of clinical trials, research study.

Cohort Study: A cohort study is a research design that follows a group of individuals over time to examine the development of outcomes or diseases. It is commonly used to investigate the causes and risk factors of diseases. Related terms: Longitudinal study, prospective study, observational study.

Confidentiality: Confidentiality in research refers to the protection of participants' personal and sensitive information from unauthorized access or disclosure. Researchers must take steps to ensure that participants' data is kept confidential and secure. Related terms: Anonymity, privacy, data protection.

Confounding Variable: A confounding variable is a factor that can affect the relationship between the independent and dependent variables in a research study. It can lead to biased or misleading results if not properly controlled for. Related terms: Confounder, bias, statistical control.

Consent Form: A consent form is a document that provides participants with information about a research study, including the purpose, risks, benefits, and procedures. It is used to obtain informed consent from participants before they enroll in a study.

Control Group: A control group is a group of participants in a research study who do not receive the treatment or intervention being tested. They are used as a comparison group to evaluate the effects of the treatment or intervention. Related terms: Experimental group, comparison group, placebo group.

Correlation Coefficient: A correlation coefficient is a statistical measure that describes the strength and direction of the relationship between two variables. It is commonly used to examine the relationships between variables in research studies. Related terms: Correlation, statistical analysis, regression analysis.

Data Management: Data management refers to the process of collecting, storing, and analyzing research data. It involves ensuring the quality, accuracy, and integrity of the data, as well as protecting the confidentiality and anonymity of participants. Related terms: Data quality, data analysis, research integrity.

Data Quality: Data quality refers to the accuracy, completeness, and reliability of research data. It is essential to ensure that data is of high quality to produce valid and reliable research findings. Related terms: Data management, data analysis, research integrity.

Debriefing: Debriefing is the process of informing participants about the purpose and results of a research study after they have completed their participation. It is an important aspect of research ethics and helps to ensure that participants are aware of the study's findings and implications. Related terms: Informed consent, research ethics, participant rights.

Deception: Deception in research refers to the practice of withholding or distorting information from participants to achieve a research goal. It is generally considered unethical and should be avoided unless absolutely necessary and approved by an institutional review board. Related terms: Deception, research ethics, informed consent.

Descriptive Study: A descriptive study is a research design that aims to describe the characteristics of a population or phenomenon. It involves the collection and analysis of data to provide a detailed description of the research topic. Related terms: Case series, case report, observational study.

Double-Blinded Study: A double-blinded study is a research design in which both the participants and the researchers are unaware of the treatment or intervention being administered. Related terms: Blinded study, single-blinded, masked.

Effect Size: Effect size is a statistical measure that describes the magnitude of the difference or relationship between variables. It is commonly used to evaluate the practical significance of research findings. Related terms: Statistical significance, practical significance, magnitude of effect.

Empirical Research: Empirical research is a type of research that involves the collection and analysis of data to test hypotheses or answer research questions. It is based on observation and experience, rather than theory or opinion. Related terms: Experimental research, quasi-experimental research, observational research.

Ethics Committee: An ethics committee is a group of individuals who review and approve research studies to ensure that they meet ethical standards and guidelines. They evaluate the potential risks and benefits of a study, as well as the informed consent process and participant protection. Related terms: Institutional review board, research ethics, ethics approval.

Exclusion Criteria: Exclusion criteria are the criteria used to determine which individuals are not eligible to participate in a research study. They are used to ensure that the study is conducted with a homogeneous group of participants and to minimize the risk of harm or adverse events. Related terms: Inclusion criteria, eligibility criteria, participant selection.

Experimental Design: An experimental design is a research design that involves the manipulation of one or more independent variables to examine their effect on a dependent variable. It is commonly used to establish cause-and-effect relationships and test hypotheses. Related terms: Quasi-experimental design, observational design, research design.

Experimental Group: An experimental group is a group of participants in a research study who receive the treatment or intervention being tested. They are compared to a control group to evaluate the effects of the treatment or intervention. Related terms: Control group, comparison group, treatment group.

External Validity: External validity refers to the generalizability of research findings to other populations, settings, or contexts. It is an important aspect of research design and involves ensuring that the study is representative of the population or phenomenon being studied. Related terms: Internal validity, generalizability, representativeness.

False Negative: A false negative is a test result that incorrectly indicates that a participant does not have a particular condition or disease. It is an important consideration in research studies, particularly in diagnostic testing and screening. Related terms: False positive, sensitivity, specificity.

False Positive: A false positive is a test result that incorrectly indicates that a participant has a particular condition or disease. Related terms: False negative, sensitivity, specificity.

Generalizability: Generalizability refers to the extent to which research findings can be applied to other populations, settings, or contexts. Related terms: External validity, internal validity, representativeness.

Hypothesis Testing: Hypothesis testing is a statistical technique used to test the significance of research findings and determine whether they support a particular hypothesis or theory. It involves the use of null and alternative hypotheses to evaluate the probability of the observed results. Related terms: Statistical analysis, hypothesis, research design.

Inclusion Criteria: Inclusion criteria are the criteria used to determine which individuals are eligible to

participate in a research study. Related terms: Exclusion criteria, eligibility criteria, participant selection.

Informed Consent: Informed consent is the process of providing participants with information about a research study, including the purpose, risks, benefits, and procedures, and obtaining their voluntary agreement to participate. It is an essential aspect of research ethics and involves ensuring that participants are aware of their rights and responsibilities. Related terms: Consent, research ethics, participant rights.

Institutional Review Board (IRB): An IRB is a committee that reviews and approves research studies to ensure that they meet ethical standards and guidelines. Related terms: Ethics committee, research ethics, ethics approval.

Internal Validity: Internal validity refers to the extent to which research findings are due to the manipulation of the independent variable and not to other factors. It is an important aspect of research design and involves ensuring that the study is free from bias and confounding variables. Related terms: External validity, generalizability, representativeness.

Intervention: An intervention is a treatment, program, or policy that is being tested or evaluated in a research study. It can be a medical treatment, a behavioral intervention, or a social program. Related terms: Treatment, program, policy.

Longitudinal Study: A longitudinal study is a research design that involves the collection of data from the same participants over a period of time. It is commonly used to examine the development of outcomes or diseases and to evaluate the effects of interventions or treatments. Related terms: Cohort study, prospective study, observational study.

Masked Study: A masked study is a research design in which one or more parties, such as the participants or researchers, are unaware of the treatment or intervention being administered. Related terms: Blinded study, double-blinded, single-blinded.

Measure of Central Tendency: A measure of central tendency is a statistical measure that describes the middle or typical value of a dataset. It can include measures such as the mean, median, or mode. Related terms: Statistical analysis, data analysis, descriptive statistics.

Meta-Analysis: A meta-analysis is a statistical technique that combines the results of multiple studies to draw more general conclusions. It is commonly used to synthesize the results of randomized controlled trials and to evaluate the effectiveness of interventions or treatments. Related terms: Systematic review, statistical analysis, research synthesis.

Non-Maleficence: Non-maleficence is the principle of doing no harm in research. It involves minimizing the risk of harm or adverse events to participants and ensuring that the benefits of the research outweigh the risks. Related terms: Beneficence, autonomy, justice.

Null Hypothesis: The null hypothesis is a statistical hypothesis that suggests that there is no significant difference or relationship between variables. It is often denoted as H0 and is used in conjunction with the alternative hypothesis to test the significance of research findings. Related terms: Alternative hypothesis,

statistical significance, hypothesis testing.

Number Needed to Treat (NNT): The NNT is a statistical measure that describes the number of participants who need to receive a treatment or intervention in order to achieve a specific outcome or benefit. It is commonly used to evaluate the effectiveness of treatments or interventions. Related terms: Effect size, statistical significance, practical significance.

Observational Study: An observational study is a research design that involves the collection of data without manipulating the independent variable. It is commonly used to examine the relationships between variables and to identify risk factors or causes of diseases. Related terms: Experimental design, quasi-experimental design, research design.

Participant Rights: Participant rights refer to the rights and protections that participants have in a research study, including the right to informed consent, confidentiality, and autonomy. Related terms: Informed consent, research ethics, human subjects protection.

Phases of Clinical Trials: The phases of clinical trials refer to the different stages of testing and evaluation of a new treatment or intervention. They include Phase I, II, III, and IV trials, each with its own specific goals and objectives. Related terms: Clinical trial, research study, treatment development.

Placebo: A placebo is a dummy treatment or intervention that is used as a control in a research study. It is designed to mimic the treatment or intervention being tested, but has no actual therapeutic effect.

Placebo Effect: The placebo effect is the phenomenon in which participants experience a real change or improvement in their condition due to their belief in the treatment or intervention, rather than the actual effect of the treatment. Related terms: Placebo, treatment effect, expectation effect.

Power Analysis: A power analysis is a statistical technique used to determine the sample size required to detect a statistically significant effect in a research study. It involves calculating the power of the study to detect a specific effect size. Related terms: Sample size, statistical analysis, hypothesis testing.

Practical Significance: Practical significance refers to the real-world importance or relevance of research findings. Related terms: Clinical significance, effect size, number needed to treat.

Predictive Validity: Predictive validity refers to the ability of a measure or instrument to predict a specific outcome or criterion. It is an important aspect of research design and involves ensuring that the measures used are reliable and valid. Related terms: Construct validity, content validity, criterion validity.

Prospective Study: A prospective study is a research design that involves the collection of data from the same participants over a period of time, with the goal of examining the development of outcomes or diseases. Related terms: Longitudinal study, cohort study, observational study.

Protocol: A protocol is a detailed plan or procedure for conducting a research study. It outlines the methods, procedures, and timeline for the study, as well as the roles and responsibilities of the researchers and participants. Related terms: Research plan, study plan, methodology.

Psychological Harm: Psychological harm refers to any negative emotional or psychological consequence of participating in a research study. It can include feelings of anxiety, stress, or trauma, and must be minimized or avoided in research studies. Related terms: Physical harm, risk, benefit.

Publication Bias: Publication bias is the tendency for researchers to publish studies with positive or significant findings, while withholding studies with negative or insignificant findings. It can lead to an exaggerated or distorted view of the effectiveness of treatments or interventions. Related terms: Selective reporting, outcome reporting bias, research integrity.

Quasi-Experimental Design: A quasi-experimental design is a research design that involves the manipulation of one or more independent variables, but lacks the control and randomization of a true experimental design. It is commonly used in field settings or when randomization is not possible. Related terms: Experimental design, observational design, research design.

Randomization: Randomization is the process of assigning participants to treatment or control groups in a research study using a random and unbiased method. It helps to minimize bias and ensure the internal validity of the study. Related terms: Random assignment, random sampling, stratification.

Randomized Controlled Trial (RCT): An RCT is a research design that involves the random assignment of participants to treatment or control groups, with the goal of evaluating the effectiveness of a treatment or intervention. It is considered the gold standard of research designs. Related terms: Clinical trial, experimental design, research study.

Regression Analysis: Regression analysis is a statistical technique used to examine the relationship between a dependent variable and one or more independent variables. It involves the use of regression equations to model the relationships between variables. Related terms: Statistical analysis, data analysis, correlation analysis.

Reliability: Reliability refers to the consistency or dependability of a measure or instrument. It is an important aspect of research design and involves ensuring that the measures used are reliable and consistent. Related terms: Validity, generalizability, research design.

Research Design: A research design is a plan or framework for conducting a research study. Related terms: Protocol, study plan, methodology.

Research Ethics: Research ethics refers to the principles and guidelines that govern the conduct of research studies, including the protection of human subjects, the use of informed consent, and the minimization of risk and harm. Related terms: Ethics, morality, human subjects protection.

Research Integrity: Research integrity refers to the honesty, transparency, and accountability of researchers in the conduct of research studies. It involves ensuring that research is conducted in an ethical and responsible manner, with attention to detail and accuracy. Related terms: Research ethics, integrity, honesty.

Research Question: A research question is a specific question or hypothesis that guides the conduct of a research study. It is often used to focus the study and ensure that the research is relevant and meaningful.

Related terms: Research hypothesis, study aim, research objective.

Research Study: A research study is a systematic investigation or inquiry into a specific topic or phenomenon. It involves the collection and analysis of data, as well as the interpretation and reporting of the results. Related terms: Research project, research design, methodology.

Risk-Benefit Ratio: The risk-benefit ratio is a calculation of the potential risks and benefits of a research study. It involves weighing the potential harm or adverse events against the potential benefits or advantages of the study. Related terms: Risk, benefit, research ethics.

Sample Size: A sample size is the number of participants or observations included in a research study. It is an important aspect of research design and involves ensuring that the sample is representative of the population or phenomenon being studied. Related terms: Power analysis, statistical analysis, hypothesis testing.

Sampling Frame: A sampling frame is the population or group from which a sample is drawn. It is an important aspect of research design and involves ensuring that the sampling frame is representative of the population or phenomenon being studied. Related terms: Sample size, statistical analysis, research design.

Selection Bias: Selection bias is a type of bias that occurs when the sample is not representative of the population or phenomenon being studied. It can occur due to factors such as non-random sampling, volunteer bias, or selective reporting. Related terms: Bias, sampling error, research design.

Sensitive Information: Sensitive information refers to any personal or confidential information that could potentially harm or embarrass participants if it is disclosed. It must be protected and kept confidential in research studies. Related terms: Confidentiality, anonymity, data protection.

Significance Level: A significance level is a threshold value used to determine whether a research finding is statistically significant. It is often set at 0.05, Which means that there is less than a 5% chance of obtaining the observed results by chance. Related terms: Statistical significance, hypothesis testing, p-value.

Single-Blinded Study: A single-blinded study is a research design in which one party, such as the participants or researchers, is unaware of the treatment or intervention being administered. Related terms: Blinded study, double-blinded, masked.

Statistical Analysis: Statistical analysis is the process of using statistical techniques to analyze and interpret research data. It involves the use of statistical software and methods to summarize and describe the data, as well as to test hypotheses and draw conclusions. Related terms: Data analysis, research design, methodology.

Statistical Significance: Statistical significance refers to the probability that a research finding is due to chance rather than a real effect. It is often evaluated using statistical tests, such as t-tests or ANOVA, and is typically set at a significance level of 0.05. Related terms: Significance level, hypothesis testing, p-value.

Stratification: Stratification is the process of dividing a sample into subgroups or strata based on specific characteristics, such as age or sex. It is often used to ensure that the sample is representative of the

population or phenomenon being studied. Related terms: Randomization, sampling, research design.

Study Plan: A study plan is a detailed outline of the procedures and timeline for conducting a research study. It includes the research question, objectives, methodology, and expected outcomes, as well as the roles and responsibilities of the researchers and participants. Related terms: Protocol, research design, methodology.

Survey Research: Survey research is a type of research that involves the collection of data through self-report measures, such as questionnaires or interviews. It is often used to gather information about attitudes, opinions, or behaviors. Related terms: Questionnaire, interview, observational study.

Systematic Review: A systematic review is a comprehensive and structured review of the literature on a specific topic or research question. It involves the use of explicit methods and criteria to identify, evaluate, and synthesize the results of relevant studies. Related terms: Meta-analysis, research synthesis, literature review.

Type I Error: A Type I error is the error of rejecting a true null hypothesis, which can occur when a statistical test is significant but the result is due to chance. It is often referred to as a false positive error. Related terms: Type II error, statistical significance, hypothesis testing.

Type II Error: A Type II error is the error of failing to reject a false null hypothesis, which can occur when a statistical test is not significant but the result is due to a real effect. It is often referred to as a false negative error. Related terms: Type I error, statistical significance, hypothesis testing.

Validity: Validity refers to the extent to which a measure or instrument accurately measures what it is supposed to measure. Related terms: Reliability, generalizability, research design.

Variable: A variable is a characteristic or attribute that is measured or observed in a research study. It can be a dependent variable, independent variable, or confounding variable, and is used to examine the relationships between variables. Related terms: Dependent variable, independent variable, confounding variable.

Volunteer Bias: Volunteer bias is a type of bias that occurs when participants self-select into a research study, which can result in a sample that is not representative of the population or phenomenon being studied. Related terms: Selection bias, sampling error, research design.

Weighted Average: A weighted average is a statistical measure that takes into account the relative importance or size of each observation or group. It is often used to combine the results of multiple studies or to calculate the overall effect size. Related terms: Average, mean, statistical analysis.