

Research Words and Definitions

Research studies can vary depending on the research question and the information the researchers want to collect. When learning about a study or deciding if you want to participate in a study, you may hear some new or different words. This glossary defines some of those words.

If a glossary word is used in a definition, its first use is **bolded**.

Adverse event	A troublesome change in the health of a research study participant . This can include a concerning test result, a hospital visit, or an uncomfortable reaction to a medication, like itching or dizziness. Sometimes, this occurs during a study. Other times, it happens after a study has ended. This change may or may not be caused by the study intervention .
Arm	Any research study group in a randomized controlled trial (RCT) . Most RCTs have 2 arms , but some have 3 or more.
Baseline	Data collected from all participants at the beginning of a research study . These data can include demographics (like age, sex, race, and ethnicity) and/or study-specific data that a researcher chooses (like blood pressure and medication use).
Bias	Prejudiced view or evaluation of a research study . If there is bias in a study, it can lose credibility. Some examples of bias are choosing which participants are in each group and asking leading questions to get a participant to say a certain answer.

<p>Blinding</p>	<p>Process through which one or more research team members is unaware which group of participants is receiving the study intervention and which group is not. Blinding helps prevent bias and information errors. It is common for researchers to be blinded in clinical trials for new medications.</p>
<p>Clinical research</p>	<p>The study of health and illness in people.</p>
<p>Clinical trial</p>	<p>A research study that looks at how well a study intervention works in people. The intervention may be a drug, medical procedure, medical device, or even a lifestyle change. There are 4 phases of clinical trials.</p>
<p>Clinical trial: Phase 1</p>	<p>A phase 1 clinical trial is usually the first research study that involves people as participants. The main reason for doing phase 1 clinical trials is to find the highest dose of the new intervention (like a new drug) that can be given safely without serious side effects. Although the intervention may have been tested in lab and animal studies, the side effects in people cannot always be predicted. These studies also help to decide on the best way to give the intervention.</p> <p><i>Phase 1 clinical trials ask the question: Is the drug safe?</i></p>

<p>Clinical trial: Phase 2</p>	<p>A phase 2 clinical trial occurs after a phase 1 clinical trial. Phase 2 clinical trials test interventions to see if they work. The type of outcome that the researchers look for depends on the study goals for the intervention. In some studies, it may mean that a medication improves blood counts. In other studies, the intervention may improve the patient’s quality of life. Many studies look to see if people receiving the intervention live longer than they would have been expected to without it.</p> <p><i>Phase 2 clinical trials ask the question: Does the treatment work?</i></p>
<p>Clinical trial: Phase 3</p>	<p>A phase 3 clinical trial occurs after a phase 2 clinical trial. Phase 3 clinical trials compare the safety and effectiveness of the intervention to the effectiveness of the standard treatment. Because researchers do not yet know which is better, participants are often randomized into different groups and receive either the standard treatment or the intervention. Phase 3 studies are large, at least 100 participants.</p> <p><i>Phase 3 clinical trials ask the question: Is the study intervention better than the standard treatment?</i></p>

<p>Clinical trial: Phase 4</p>	<p>Phase 4 clinical trials occur after a phase 3 clinical trial. Drugs approved by the Food and Drug Administration (FDA) are often watched for a long period of time in a phase 4 clinical trial. Even after testing an intervention on thousands of people, its full effects still may not be known. Some questions may still need to be answered and may take many years to answer. For example, a drug may get FDA approval because it was shown to improve blood counts, but there are still some questions:</p> <ul style="list-style-type: none"> • Are people who take the drug more likely to live longer than people with the same illness who do not take the drug? • Does the drug have rare side effects that haven't been seen yet? • Does the drug have side effects that only show up after a person has taken it for a long time? <p><i>Phase 4 clinical trials ask the question: What else do we need to know?</i></p>
<p>Confidentiality</p>	<p>Assurance that a participant's information will be kept secret. Only authorized people will have access.</p>
<p>Control group</p>	<p>Group of research study participants who are not treated with the study intervention. The participants in this group receive the standard treatment, a different intervention, or a placebo. The data from this group are compared to the data from the experimental group to help determine the effectiveness of the intervention.</p>
<p>Data</p>	<p>Information that is collected during a research study. Examples are observations, measurements (like blood pressure), and other facts.</p>

Effectiveness	Determination of how well an intervention works. Researchers use the study's outcomes to help determine the effectiveness of an intervention. An effective intervention will improve health and/or prevent a disease.
Eligibility criteria	Key requirements that must be met by people who want to participate in a research study . There are 2 types of eligibility criteria : inclusion criteria and exclusion criteria .
Engagement	Meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders throughout the research process—from topic selection through design and conduct of research to dissemination of results.
Enrollment	Number of participants in a research study .
Exclusion criteria	Type of eligibility criteria . These are reasons that <i>prevent</i> a person from participating in a research study . They are different for each study.
Experimental group	Group of research study participants receive the intervention . The data from this group is compared to the data from the control group to help determine the effectiveness of the intervention.
Focus group	Small group of people brought together to discuss a research question . Conversation is guided by a research team member. It is an opportunity for individuals to share their perspectives and opinions.

Food and Drug Administration (FDA)	Agency within the U.S. Department of Health and Human Resources that is responsible for protecting the public health by assuring the safety, effectiveness , quality, and security of human drugs, vaccines, and medical devices.
Inclusion criteria	Type of eligibility criteria . These are reasons that <i>allow</i> a person to participate in a research study . They are different for each study.
Informed consent	Process that researchers use to provide important information about a research study before people decide whether or not to participate. This information includes potential risks and benefits of participating in the study. Participants must sign an informed consent form before being in a study, which usually includes: <ul style="list-style-type: none"> • The purpose of the study • What participants will be asked to do • What risks or benefits might be involved • How long the study will take and where it will happen • Who to contact for more information
Institutional Review Board (IRB)	Group of people who review, approve, and monitor a research study's written protocol . They make sure that the researchers are protecting the rights and welfare of study participants . The group typically includes people with different backgrounds, including a local community member.
Intervention	Process, action, treatment that is the focus of a research study . Examples of interventions are drugs, medical procedures, and medical devices. Interventions can be health education, diet changes, and exercise changes.

<p>Observational study</p>	<p>Type of research study in which participants belong either to the control group or to the experimental group and are assessed for health outcomes. The researcher does not assign participants to their groups. Participants may receive different types of interventions during the study.</p>
<p>Outcome</p>	<p>Result of a research study that is used to assess the effectiveness of a study intervention. Some examples are symptom relief, hospitalization, and improved quality of life.</p>
<p>Participant</p>	<p>Person who volunteers to be in a research study.</p>
<p>Patient-reported outcomes</p>	<p>These outcomes assess the impact of a health condition and/or intervention from the patient’s perspective. This allows patients to share health information that may be difficult for their doctor or a researcher to recognize without the patient’s input. Some examples are symptoms and quality of life.</p>
<p>Pilot study</p>	<p>A small, preliminary research study that happens before a larger, final study. Pilot studies help researchers evaluate the feasibility, time, and cost of the larger study. These studies also help researchers identify any problems with the study design, study methods, and other parts of the study.</p> <p><i>Pilot studies ask the question: Should the intervention be studied on a larger scale?</i></p>
<p>Placebo</p>	<p>A sham pill, inactive ingredient, or fake intervention used in some types of research studies to help make sure outcomes are not biased. A placebo pill is sometimes called a “sugar pill.”</p>

<p>Pragmatic trial</p>	<p>A clinical trial that tests the effectiveness of an intervention under real-world conditions, rather than with the use of strict eligibility criteria. <i>Pragmatic trials ask the question: Does the intervention work in routine, clinical practice with a wide range of patients?</i></p>
<p>Principal Investigator</p>	<p>Researcher with primary responsibility for designing and conducting a research study.</p>
<p>Protocol</p>	<p>Written plan for a research study. It includes study goals, study design, and study methods. It may also include background information about the research question.</p>
<p>Publication</p>	<p>Written report that summarizes a research study, including the study methods, data, and outcomes.</p>

<p>Randomization</p>	<p>The process of assigning each participant to either the control group or the experimental group without the researcher choosing the participants in each group.</p> <p>Randomization helps remove the researcher's bias and is used to help reduce the chance that one group of participants is significantly different than the other group. It is important to make sure that the groups have people in similar states of health so that the outcomes are not skewed in favor of one group. If people were allowed to choose their group (either the control group or the experimental group), the outcomes might not be as accurate.</p> <p>For example, if the experimental group has sicker participants, then the intervention might now work as well. Researchers could not be sure if this was because the intervention wasn't as good as the standard treatment or because it was tested in sicker people. If the participants are randomized and the groups are not significantly different, then the researcher can be more certain that the intervention is the cause of the study's outcomes.</p> <p>Participants often have a 50-50 chance of being in the control group or the experimental group. In some cases, the study design may allow for a different ratio, like 2 out of 3 people receiving the intervention and 1 out of 3 people not receiving the intervention.</p>
<p>Randomized controlled trial (RCT)</p>	<p>A research study that uses a randomization process to assign participants to either the experimental group or the control group.</p>
<p>Recruitment</p>	<p>Asking people participate in a research study. The researcher will only ask people who meet the study's eligibility requirements and complete the screening process.</p>

Research	A process that helps discover new knowledge. It is the gathering of information or testing of an idea. This process helps us understand more about a research question .
Researcher	Person involved in conducting a research study .
Research Assistant	Research team member who is responsible for various activities of a research study , like data collection, data entry, and other administrative tasks.
Research Question	What the researcher wants to answer by conducting a research study .
Research Study	Investigation that aims to answer a particular research question .
Research Team	All members involved with a research study . The research team is led by the principal investigator and can include other members like a study coordinator and a research assistant .
Risk	Potential harm that could occur from participating in a research study . Some examples are an unpleasant side effect from the intervention and a loss of confidentiality .
Screening	A process that happens before people can be recruited to be in a research study . Researchers make sure the potential participants meet the study's eligibility criteria and are good candidates for the study.

Stakeholder	A person or community who has a stake in the topic of interest. A healthcare stakeholder is a person or community who has a stake in the effectiveness of our healthcare system. Healthcare stakeholders include patients, family members, caregivers, medical providers, payers, industry, policy makers, and researchers , among others.
Standard treatment	A medical treatment that doctors currently use to treat a specific disease or condition. It is approved by the Food and Drug Administration (FDA) .
Study coordinator	Research team member who is responsible for managing the daily activities of a research study . This person works closely with the study's principal investigator and other research team members.
Study design	Scientific approach that a researcher uses to answer a research question . It outlines how and when to collect specific data and other information during a research study .
Study methods	Systematic approach to conducting a research study . This includes a steps involved with various parts of the study, like data collection and data analysis.
Sponsor	A person, organization, company, institution, or government agency that provides money or other resources for a research study .

Withdrawal from study	A participant's decision to leave or quit a research study . The participant should tell the research team when they leave, but the participant does not have to share the reasons why. The participant can make the decision to leave or quit at any point during the study without penalty.
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