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.
Blinding	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.
Clinical research	The study of health and illness in people.
Clinical trial	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**.
Clinical trial: Phase 1	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. *Phase 1 clinical trials ask the question: Is the drug safe?*

Clinical trial: Phase 2	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. *Phase 2 clinical trials ask the question: Does the treatment work?*
Clinical trial: Phase 3	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. *Phase 3 clinical trials ask the question: Is the study intervention better than the standard treatment?*

Clinical trial: Phase 4	**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: • 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? *Phase 4 clinical trials ask the question: What else do we need to know?*
Confidentiality	Assurance that a **participant's** information will be kept secret. Only authorized people will have access.
Control group	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.
Data	Information that is collected during a **research study**. Examples are observations, measurements (like blood pressure), and other facts.

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 *prevent* 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 *allow* 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: • 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.

Observational study	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.
Outcome	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.
Participant	Person who volunteers to be in a **research study**.
Patient-reported outcomes	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.
Pilot study	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. *Pilot studies ask the question: Should the **intervention** be studied on a larger scale?*
Placebo	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."

Pragmatic trial	A **clinical trial** that tests the **effectiveness** of an **intervention** under real-world conditions, rather than with the use of strict **eligibility criteria**. ***Pragmatic trials*** *ask the question: Does the intervention work in routine, clinical practice with a wide range of patients?*
Principal Investigator	Researcher with primary responsibility for designing and conducting a **research study**.
Protocol	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**.
Publication	Written report that summarizes a **research study**, including the **study methods**, **data**, and **outcomes**.

Randomization	The process of assigning each **participant** to either the **control group** or the **experimental group** without the **researcher** choosing the participants in each group. **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. 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**. 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.
Randomized controlled trial (RCT)	A **research study** that uses a **randomization** process to assign **participants** to either the **experimental group** or the **control group**.
Recruitment	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.

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.