

UCLA Health



— All About —
Clinical Trials

What is clinical research?



Clinical research is the study of health and disease in humans

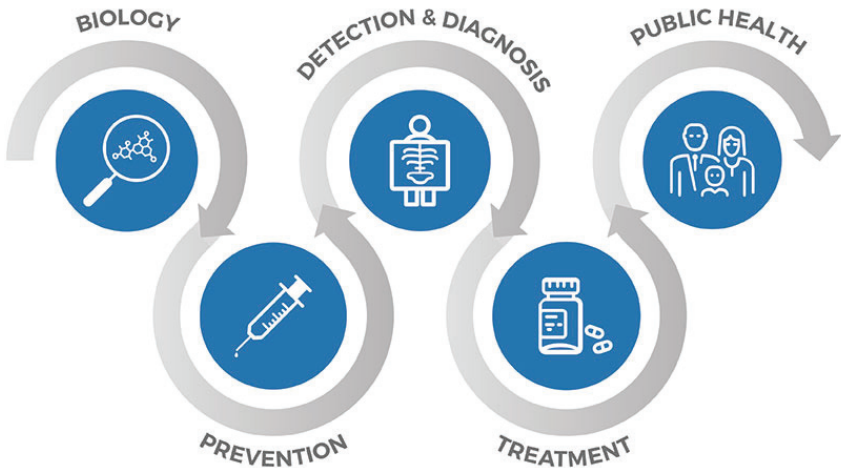
- Clinical research is important to find better ways to prevent, diagnose and treat disease.
- Both healthy people and people with an illness are included in clinical research.
- Research staff must get your verbal or written permission before you can take part in research.

What are the different types of clinical research studies?

There are many different types of clinical research studies.

- **Genetic** - Learn who gets a disease by researching how genes and illness may be related
- **Screening** - Try to find the best way to detect a certain disease
- **Diagnostic** - Test better ways to identify a disease
- **Treatment** - Test medications in people with disease
- **Prevention** - Look for ways to prevent disease

Cancer Research Continuum



What are the different phases of clinical trials?

The are four different phases of clinical trials:

- **Phase 1**

Researchers test a new drug or treatment for the first time in a small group of people to test safety, side effects and dose.

- **Phase 2**

The drug or treatment is tested in a larger group of people to see if it works and to check safety.

- **Phase 3**

The drug or treatment is given to a larger group of people to make sure that it works, track any side effects and compare it to usual treatments.

- **Phase 4**

Studies are done after the drug or treatment is approved to collect information on effects in different groups and any problems with long-term use.



PHASE
1

PHASE
2

PHASE
3

PHASE
4

What happens if I decide to participate in a clinical trial?



Once you decide to take part in a clinical trial, you can expect:

- A member of the research team will give you more information about the study and will tell you exactly what will happen next.
- You will need to give your signature or verbal permission to show that you know your rights and agree to participate in the study.
- If the study involves biobanking, your samples will be collected and stored until needed for research.
- Researchers might contact you for future studies.
- You can always ask questions if there is something you do not understand!

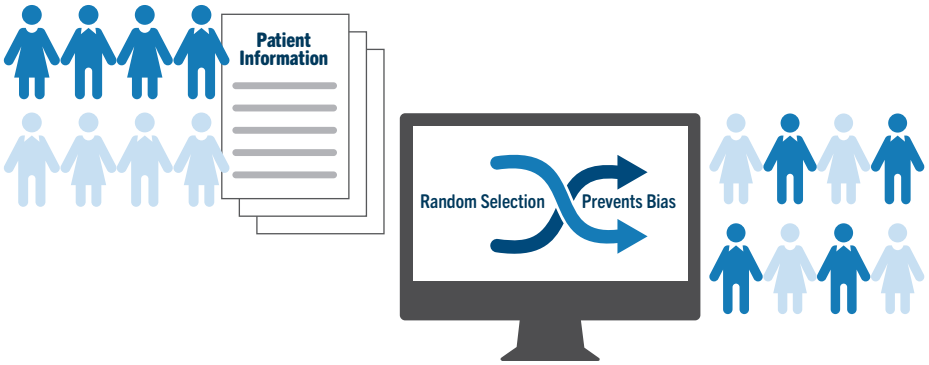
What is “informed consent”?

Informed consent is the process of providing you with important details about a clinical trial before you decide to participate.

- Researchers will explain the study’s risks and benefits, as well as your rights as a participant. You should feel free to ask any questions.
- If you agree to take part in the study, you will sign a consent form which shows that you understand your rights and role in the study.
- Informed consent is not a contract, and you are free to leave the study at any time.



What is a “randomized” study?



A randomized study is a study that places participants into different groups by chance.

- A “control group” is a group of people in a study who receive standard of care (the typical treatment). They do not receive the trial treatment.
- A “treatment group” is a group of people in a study who receive the trial treatment. Researchers measure the effects of new treatments from this group.
- You don’t get to pick which group you will be in. Researchers don’t get to pick your group either. A computer places you into a group at random. It’s like flipping a coin to get heads or tails.
- This is done to avoid any bias, or unfairness, in who gets put into one group vs. another.

What is a placebo?

A placebo is a harmless pill, liquid or powder that has no effects, sometimes known as a “sugar pill.”

- Placebos help researchers figure out if a new treatment works. Researchers compare people receiving a placebo to people receiving a trial treatment.
- The people who receive the placebo are usually in a “control group.”
- A researcher will tell you if placebos are used in the study before you enter a trial.



Standard
Treatment
+
Placebo
“Control
Group”

Standard
Treatment
+
Study Drug
“Treatment
Group”

What is a “blinded” study?

“Blinded” studies are designed to prevent members of the research team or study participants from influencing the results.

- In a **single-blind** study, people participating in the study are not told whether they are being given a placebo or an active treatment, but the research team knows.
- In a **double-blind** study, neither the study participants nor the research team are told who is receiving a placebo or an active treatment, but the pharmacist knows.
- It is always possible, if medically necessary, to find out which treatment you are receiving.

Will I get the results of the research?

- You may or may not receive the results of the research, depending on the study. You can ask the research staff if you are interested in the results of the study.
- If researchers publish results of the study in medical journals, the results will not have any personal information about you.



Why should I trust clinical trials?



- Before you enroll, research staff will tell you all about the trial and answer any questions you have.
- Research staff will explain any treatments and tests that are part of the study.
- It is required by law that research staff keep all information protected.

Clinical trial myths vs. facts

- **Myth:** Once I join a study, I cannot change my mind.

Fact: You can change your mind and leave the study at any time.

- **Myth:** If I donate samples, someone will be able to identify me.

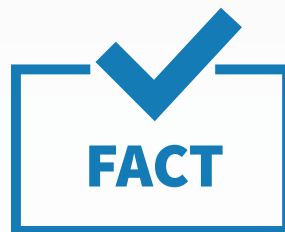
Fact: Samples do not contain personal information. Donated samples are labeled with special codes.

- **Myth:** If I do not get placed into the treatment group, I will not get the right medicine or treatment for my disease.

Fact: You will always receive the best available care for your condition, regardless of which group you are placed into.

- **Myth:** In a clinical trial, I am a guinea pig.

Fact: Researchers follow rules to ensure you are always treated with respect and receive quality care, maximum benefits and minimal harm.



Who can see my information?

Only research staff can see your information. These researchers have special training on how to protect your privacy.

- Sometimes researchers share study details with other researchers. If they do, they will not include information that can identify you.
- Before you join a study, you sign a consent form to show that you have talked to the researchers about the study and you understand your rights and your role in the study. This might mean researchers can store your information in a secure database. Your consent form will list the people who can see your information.
- If researchers collect information that can identify you, they will keep this information separate from other information. Information that can identify you has extra levels of protection to keep it safe.



What are the benefits of participating in a clinical trial?

There are many possible benefits to taking part in a clinical trial:

- You may have access to a new treatment not available outside of the trial.
- You may be among the first patients to benefit from a new treatment.
- You will receive close monitoring and care from the research team.
- You may feel more control over your condition as you take an active role in treating your illness.
- The trial may help doctors learn how to better treat your illness, which can help many patients.
- All your personal information will be kept completely confidential.

**Research staff
will explain any specific
benefits of taking part
in a particular study.**

What is the downside to participating in a study?

**People can decide not to take part in a clinical trial.
Some things to consider include:**

- Risks of participating. Risks are different for each study, and a recruiter will discuss these with you.
- How long a person needs to take part in the study
- Where and when the appointments are scheduled

Other reasons you may not want to participate:

- You might be concerned about accidental release of your personal information. Every study has security measures to prevent this from happening.
- You may feel more comfortable sticking with your routine care.
- Participating in a clinical trial is not for everyone. You should discuss all treatment options with your doctor before deciding what is right for you.

What are my rights as a research participant?



You have a right to:

- Safe and respectful care
- Be fully informed about your diagnosis and treatment plan
- Decide not to take part in a study
- Leave a study at any time
- Ask for information in the language of your choice or ask for an interpreter

Please note:

- You will not be treated differently because of your ethnicity, sex or age.
- These are your rights whether you choose to take part in a study or not.
- Those with special needs can receive additional assistance.

Will a research study affect my care?

- You can choose to take part in a study, or you may choose not to be part of a study.
- You can decide to leave a study at **any time**.
- It is important you talk to your doctor about any concerns before leaving a study. Your doctor can tell you about any medical risks of leaving a study.

Can I change my mind?

- The consent form has details on how to leave the study, including a telephone number. You will be given a consent form when a researcher explains the study to you.
- Research staff can also help you leave a study.

Participating in a study will not:

- Change the quality of medical care you receive
- Deny you care at your medical institution
- Change your relationship with your doctor

Why does diversity matter in clinical trials?

- Most people who take part in clinical trials are white. Racial and ethnic minority groups make up less than 10% of all clinical trial participants. This is a problem because some minority groups get certain diseases more often than others.
- A person's response to diseases and medications can depend on many things, including a person's genes, ethnicity, sex and lifestyle. Groups can process medications differently, so medications that work for one group may not work for another.
- It is important to have diverse groups of people taking part in clinical trials to make sure new treatments and medications work for people of all backgrounds.



How do I know that negative research events from the past won't happen again?

Today, researchers learn to acknowledge and prevent the mistakes of our past:

- In the Tuskegee Study (1932-1972) researchers did not tell participants all the study information and withheld medical treatment from participants. By today's standards, participants could not join a study without all the relevant information, and research studies cannot prevent high-quality medical care.
- Henrietta Lacks received a medical procedure in 1951. Medical research staff did not inform her about using a sample of her cells from the procedure. Today, a study cannot use someone's cells unless they consent to the research plan.
- Today, the FDA oversees clinical studies, and each research site also has an Institutional Review Board (IRB) that makes sure researchers follow all ethical guidelines and laws.

References

Health for All | Real Talk: Clinical Trials (2022).

Available at: healthforallproject.org

Langford, A., Studts, J.L. and Byrne, M.M. (2021). 'Improving knowledge and decision readiness to participate in cancer clinical trials: Effects of a plain language decision aid for minority cancer survivors,' *Patient Education and Counseling*, 104(2), pp. 422–426. doi:10.1016/j.pec.2020.07.005.

NIH Clinical Research Trials and You.

Available at:

nih.gov/health-information/nih-clinical-research-trials-you

Simon, M.A., et al. (2019) 'Improving Research Literacy in Diverse Minority Populations with a Novel Communication Tool,' *Journal of Cancer Education*, 34(6), pp. 1120–1129. doi:10.1007/s13187-018-1418-5.

Torres, S., et al. (2015) 'The Development of a Communication Tool to Facilitate the Cancer Trial Recruitment Process and Increase Research Literacy among Underrepresented Populations,' *Journal of Cancer Education*, 30(4), pp. 792–798. doi:10.1007/s13187-015-0818-z.

Understanding Clinical Trials (2022).

Available at:

umiamihealth.org/en/clinical-trials/understanding-clinical-trials

Find
UCLA Health
clinical trials: uclahealth.org/clinical-trials

UCLA Health

uclahealth.org | 310-825-2631

Copyright © 2022 by UCLA Health.
All rights reserved.