Why **Joining** a Clinical Trial **Matters**







Treatments and vaccines for COVID-19 need to be as safe and effective as possible for everyone who will use them.

Mistrust and other barriers to participation have kept many people, including those in the communities hardest hit by the pandemic, from volunteering for research studies. Although the mistrust has been earned — through historical injustices and exclusions from research in the past — including people from every community is very important. It gives us better information about how drugs or vaccines work for different people.

Here are three reasons why it is more important than ever for clinical trial volunteers to be of all ages, races, ethnicities, genders, and physical abilities and to have different underlying health conditions.

- Data from research studies play a critical role in how the U.S. Food and Drug Administration (FDA) decides whether drugs, devices, and vaccines are safe and effective to use. If a study or trial does not include a wide range of people, the FDA cannot know how safe and effective the drug or device will be for different people.
- 2. Different people respond differently to drugs and other treatments. A person's age, race, ethnicity, sex, body weight, and overall health can affect how they respond to a drug or other treatment and may affect the risk of harmful reactions.
- 3. Where people live, work, and play, as well as their overall health, can put them at higher risk for certain diseases. It is important for researchers to understand how a drug or treatment will affect the people most likely to need it.

How am I protected if I join a clinical trial?

If you choose to volunteer, your rights and well-being are protected. Major changes have been made to how clinical trials are conducted today, as scientists have learned from past mistakes. Every study must follow strict rules for safety and undergo rigorous review before, during, and after the study. Critical steps are required to make sure that all volunteers and their personal information remain as safe and protected as possible.

All government-funded clinical trials in the United States are approved and monitored at several different levels, including by independent groups called institutional review boards, which are separate from the people conducting the studies. Learn more about research protections from the HHS Office of Human Research Protections.





It is critical that the people in a clinical trial represent everyone who will use the medicine or vaccine being tested. This is especially true for studies looking at treatments and vaccines for COVID-19. Now is the time for people from every walk of life to consider joining a COVID-19 clinical trial or study.

You can play a role in making sure that the drugs and vaccines developed to prevent and fight COVID-19 are as safe and effective as possible for everyone.

Learn more about current clinical trials for the treatment and prevention of COVID-19 and how to participate at <u>combatcovid.hhs.gov</u>.

Learn more about NIH's efforts to tackle community mistrust of research head-on through <u>two-way community</u> <u>engagement and dialogue about COVID-19</u>.

