

Eligibility Criteria for Clinical Trials

All clinical trials need participants to help researchers learn how new treatments or vaccines work and how safe they are.

While some people may be very willing to participate, they may not be able to because of the trial's eligibility criteria.



What does eligibility criteria mean?

Eligibility criteria are all the requirements for a person to be in a clinical trial. There are 2 parts to this:

 **Inclusion** criteria are requirements a person **must have** to be able to join a trial

 **Exclusion** criteria are anything a person **cannot have** to be able to join a trial

A person must meet **all** of the inclusion criteria to be in the trial. But, if someone has **any** of the exclusion criteria, then they cannot participate.

Here are some examples. Sometimes, what is inclusion criteria for one trial can be exclusion criteria for another.

Inclusion criteria	Exclusion criteria
Have a specific health condition	Have a health problem that would make the trial treatment unsafe
Are of a certain race or ethnicity (this helps researchers make sure treatments work for everyone)	Have a medical condition that would make the treatment not work as it should
Are currently taking certain treatments	Are currently taking treatments that would make the trial treatment unsafe
Are able and willing to do certain procedures, like providing a tumor sample	Have a test, like a blood test, that might mean the person is not healthy enough to participate
Had past treatments that did not help	Had past treatments that would affect the way the trial treatment works
Have no other treatment options	Not in good health
Are within an age, height, or weight range	Have a history of drinking alcohol or smoking

Why are eligibility criteria important?

Eligibility criteria help make sure researchers get the most accurate results possible. It also helps make sure participants are as safe as possible. This is why even if someone would really like to be in a trial, a doctor or researcher may say that they cannot participate because of the eligibility criteria.

Some researchers might use the terms “screen fail” or “failed to qualify”. This only means that the trial was not a good fit for someone based on the eligibility criteria.



What can you do when you are not accepted in a trial?

If you weren't accepted to join a trial, you can ask the trial team to explain why you weren't included. If you feel you have not had your questions answered, you can also contact the ethics committee that approved the trial.

You can talk to the trial team to find out how to contact them. The Informed Consent Form (ICF) for the trial should have the ethics committee's contact information.

Can you join other trials?



There may be other trials you are able to join. See CISCRP's [How to Find a Clinical Trial](#) brochure for more info. It's a good idea to talk to the trial team about the eligibility criteria to understand why you may or may not be able to join. The ICF for a trial should also help explain the criteria.

If you aren't eligible for a trial, there are other ways to get involved:



Participate in an observational study that only collects health data



Join an advisory board, review panel, or advocacy group to help shape the eligibility criteria that trials have and improve the trial experience for others



Talk with your family and friends to raise awareness about clinical research in your community

Researchers should be making every effort to improve eligibility criteria for trials and find ways to be inclusive of more people. Getting involved in these ways can help make change faster.

Visit CISCRP's Website to Learn More at ciscrp.org/education-center



A panel of patients, professionals, and members of the public reviewed this educational brochure.