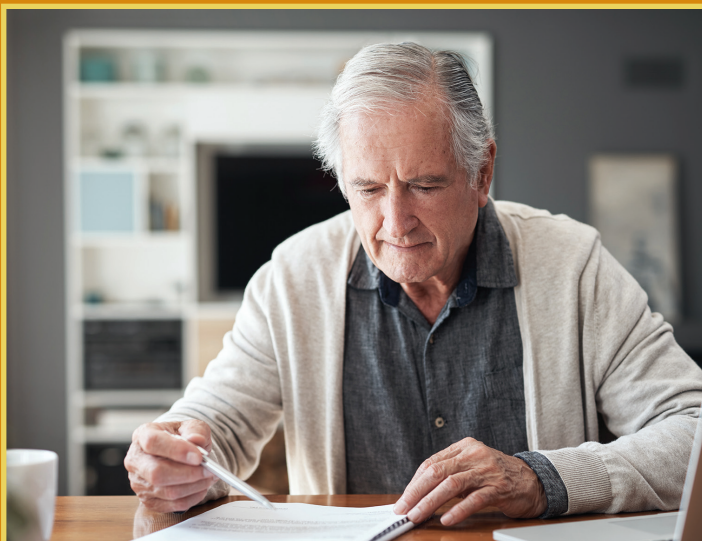


A Guide to Costs and Payments in Clinical Trials

This brochure gives you the basic facts about costs and payments in clinical trials. It also suggests some questions to ask the doctors and staff of a specific trial.



CISCRP

The Center for Information & Study
on Clinical Research Participation

Will there be any cost to me?

Usually, most of the costs in a trial are covered by the trial sponsor. The sponsor is the organization that funds and conducts the trial. Every trial has an Informed Consent Form that explains the possible costs, payments you may receive, and expenses that will be covered.

In addition to travel costs like taxi, gas mileage, or hotel, a trial may require that you take time away from work. There could also be costs for the care you receive in a trial. Some of those costs can be covered by health insurance. If there are costs that insurance might not cover, the Informed Consent Form will explain those costs.



Health insurance and clinical trials

You do not need to have health insurance to participate in a clinical trial. If you do not have insurance, you should speak to the trial staff about your payment options. Some trial sponsors have programs in place to pay for care that would normally be covered by insurance.

If you do have insurance, coverage works the same way it would for your usual healthcare. So, the requirements for copayments and deductibles are usually the same.

Insurance plans will only cover care in trials that are approved by an Institutional Review Board, also called an IRB. Most health insurers cannot refuse to let you join an approved clinical trial or limit your benefits because you are participating.

Talk to your health insurance provider

Before joining a trial, it is important to ask your health insurance provider what trial costs they will cover. Some insurance plans may not cover the routine care that the trial requires.

If your insurance plan does not have out-of-network coverage, then the trial care must be in-network to be covered. Tell your insurance provider the name of the trial site where you will receive care to find out if it is in your network.

Some insurance plans will cover trial care only if it is for a life-threatening condition. The definition of life-threatening can be different among insurance carriers, so it is important to ask.

Ask your insurance provider about their policies for addressing complications or medical problems caused by participating in a trial. They usually consider these coverage requests on a case-by-case basis.

Costs that may not be covered by health insurance

Often, clinical trials include physical examinations and procedures that would be done as part of routine care. These would be covered by health insurance. If there are tests or procedures needed only for the trial, these may not be covered. For example, the trial doctor may do blood tests to collect information specifically for the trial. While health insurers may not cover the cost for these tests, the trial sponsor may do so.



Will I be paid, and will my costs be covered?

Each trial will have its own guidelines that tell you if you will be paid and how much cost will be covered.



Payments in clinical trials

Payments in trials are made for your time and possible inconvenience of participating in the trial. These payments are also called compensation or stipends. The amount is usually based on the trial length, number of visits, the types of procedures, and other factors.



Reimbursement in clinical trials

Reimbursement is different from a stipend because it means being repaid for actual trial-related costs you covered. These expenses might be related to travel to and from the trial site, or hotel stays. You may need to show the trial staff a receipt for your expenses.



Fair payments in clinical trials

Any reimbursement or payment must be approved by an Institutional Review Board to make sure that it is reasonable. The United States Food and Drug Administration (FDA) and the National Institutes of Health (NIH) have regulations in place to make sure that clinical trial payments are reasonable.



Receiving payments in clinical trials

If your trial offers reimbursement or payment of any sort, there are different ways that you may receive it. You might get cash or a check. You could receive a card that works like a debit card, where money is automatically deposited.



Taxes on payments in clinical trials

If you receive compensation for being in a trial, you may have to report it on your taxes. If you receive \$600 or more in a year, the trial site will send you an IRS Form 1099. Include this with your tax return and report the amount you received. You do not need to report any reimbursement you receive for your expenses related to being in the trial.

Questions to ask

If you are thinking about joining a clinical trial, make sure you find out all you can about the costs and payment or reimbursement options.

Questions to ask the trial staff:

- What costs might I be responsible for?
- Will the trial sponsor reimburse me for travel or other expenses?
- Is there a limit on reimbursement?
- How often will I need to visit the trial site?
- How might the trial affect my daily life?
- What happens if I lose health insurance coverage while I am participating in the trial?
- Has it been difficult for other trial participants to get insurance coverage for trial care?

Questions to ask your health insurance provider:

- What costs will you cover if I participate in a clinical trial?
 - Will you cover routine care that the trial requires?
 - Is care at my trial site in-network?
 - If I have complications or medical problems due to participating in a trial, will you cover these costs?
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General resources

CISCRP's Education Center

You may have many other questions about clinical research. CISCRP's website has videos, brochures, FAQs, Questions to Ask, and other resources to help you learn more.

| www.CISCRP.org/education-center 1-877 MED HERO

Search Clinical Trials

If you are ready to find trials in your area, CISCRP's free service will provide you a list of relevant trials for discussion with your trusted doctors, family, and friends.

| searchclinicaltrials.org 1-877 MED HERO

ClinicalTrials.gov

Available in both English & Spanish, this website is run by the National Institutes of Health. It provides education about clinical trials and lists many of the trials taking place in the United States.

| www.clinicaltrials.gov 1-800-411-1222



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CISCRP does not recruit patients for clinical trials and does not conduct clinical research. CISCRP is also known as the Center for Information and Study on Clinical Research Participation.

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