

Novel Coronavirus (COVID-19)

Guidance for People Interested in Clinical/Vaccine Trials

As you may have heard, there is an urgent need for both vaccines and effective treatments for coronavirus (COVID-19) to control the pandemic. Vaccines and treatments are tested through controlled clinical trials to determine if they are effective and to assure that they have no harmful side effects. Many national clinical trials are currently or will soon be enrolling participants at sites in Los Angeles County. You may already have heard about one or been invited to participate by a clinic or physician. This document provides guidance on some questions to ask and a framework to help you decide if participation in a clinical trial is right for you.

Researchers for clinical trials will be reaching out to various communities across the County because it is important that vaccine and drug research include people from many different backgrounds to assess if a new treatment or vaccine will work for everyone and to give everyone eligible a chance to participate in the trial if they choose.

The Department of Public Health may, from time to time, share lists of COVID-19 research studies that are being supported by the federal government, but neither the Department of Public Health nor the County will endorse or recommend any particular clinical trial.

Rather, the choice to participate is left to each individual to decide.

Remember that it is always entirely up to you whether to participate in a clinical trial or any other kind of health research. The researchers will provide you a lot of specific information about the study and then will ask you to provide your written informed consent before you start. There is no need to make your decision quickly. You can ask the researchers for additional information or, if you need more time to decide, simply tell them.

Be aware of possible scams. Clinical research staff should not ask you to pay to participate in research or ask for private information such as your social security number, bank account or credit card numbers, or immigration status.

As you consider whether to participate, you may want to consult your healthcare provider or anyone else you trust for advice before making your decision.

The following are some questions you may want to ask before deciding to participate in a clinical drug or vaccine trial.

- **What type of vaccine or treatment is being tested? What is it intended to treat or prevent?**

There are many different treatments and vaccines being tested today for coronavirus.

- **In what phase of clinical trials is the treatment or vaccine?**

Clinical trials are a kind of clinical research used to test interventions such as drugs or vaccines. Clinical trials are often conducted in four phases. The trials at each phase have a different purpose and help

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scientists answer different questions. Refer to the Food and Drug Administration (FDA) website for more information on [clinical research](#).

- During Phase 1 clinical trials a small number of participants are used. These trials are usually the first time the treatment or vaccine is tested in people. Trials in this phase are used to test overall safety and to determine the safest dose of the treatment or vaccine.
- During Phase 2 clinical trials the experimental treatment or vaccine is tested on a larger group of people (up to several hundred), to see if it's effective and to continue to test its safety.
- During Phase 3 clinical trials the experimental treatment or vaccine is tested on much larger groups of people and these trials are usually what the agencies such as the FDA use to determine whether a drug should be approved for use. These trials provide more information on the drug's effectiveness, monitor side effects and compare it to other commonly used treatments.
- Phase 4 trials are also called post-marketing research which means it is done after receiving FDA approval for use. Studies done at this stage help to evaluate the long-term risks and benefits of the treatment or vaccine. This phase can also determine more about the side effects, interactions with other drugs, and how well it works when it's more widely used.

- **How will the clinical trial work?**

You may want to ask for more information on the details of the study. For example a randomized controlled trial is where one or more groups of people are given a treatment or vaccine and one group of people is given what is called a placebo, or something that looks like a drug or vaccine but does not have any effects. Most often, participants are randomly assigned to receive either the active drug or vaccine or the placebo, so that the two groups are as similar as possible. Neither the participant nor the researcher will know if the participant is receiving a placebo or the actual treatment. That way, the results are not biased by what one hopes or expects to find, and the study can tell if the treatment or the vaccine is truly effective. You may want to be sure you understand how people are assigned to different groups in the study as well as what exactly is provided to the participants in the different groups.

- **Has the safety of the vaccine or treatment already been assessed?**

If so, you will want to know if the vaccine or treatment has already been through a previous phase of testing that has assessed its safety. Find out what, if any, side effects were identified during the earlier phases of the study. If not, you have to consider whether you want to take part in determining the safety and side effects of the vaccine or treatment or wait until these have already been assessed.

- **How long will the study last and how much time will it take?**

Check to see if you can fit the trial into your schedule. A trial can last for a short time or a long time and take up varying amounts of your time per week or month.

- **What do I have to do?**

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You may be asked to do different things during the trial, and it will be important for you to find this out ahead of time.

- **Why have I been asked?**

You may wonder why they have selected you in particular. It is important for many different types of people to be included in trials.

- **Will I be compensated to participate?**

Find out if you may be given an incentive such as a gift card or voucher to participate in a trial and/or reimbursed for any expenses such as parking.

- **What are the risks to me?**

Though clinical trials must be designed to be as safe as possible, there is always the possibility or risk of an unexpected side effect or bad reaction. It is important for you to confirm that the basic safety of the drug or vaccine has been tested previously and if side effects or reactions have occurred.

- **If something unexpected happens to me how will I get healthcare for it? Will I go to the same clinic or doctor that I usually go to?**

You are entitled to know how you will get care if you need it due to something that happens in the trial.

- **What are the benefits to me?**

Sometimes there are benefits to you personally for participating in a study, such as extra care or tests not usually available, and sometimes the benefit is simply in helping to find effective treatments or vaccines for this pandemic. There are overall benefits to people in Los Angeles in general if an effective vaccine or treatment for coronavirus is discovered.

- **What will happen if I choose not to participate or I drop out of the trial? Will I lose out on healthcare or other benefits?**

Your decision to participate in a clinical trial is totally up to you. You should not lose out on any benefits like Medi-Cal/Medicare/health insurance you are already receiving or get in trouble in any way if you choose not to participate or to drop out at any time.

Remember – these are only suggestions!

You may have more questions you want to ask the study coordinator. You should not feel pressure to participate in any study until all of your questions have been answered. Researchers cannot include you in a study until they ensure that they have your informed consent which means that they have reviewed the study or trial with you, including the risks and benefits of participating, and have ensured that you fully understand the medical information that is shared with you. They are also required to explain that the decision to participate is completely voluntary.

Be aware of possible scams. Researchers should not be asking you to pay to participate in the research or ask for private information such as your social security number, bank account numbers or immigration status.