

A Guide to Clinical Trials for LGBTQ+ Communities

Finding Treatments Together



CISCRP

Center for Information & Study
on Clinical Research Participation

Why are clinical trials important?

Clinical trials are the best way to find out if new treatments or vaccines work and how safe they are. If clinical trials show that a new treatment or vaccine works and is safe, then it can be approved for the people who need it.

Not all clinical trials test a new treatment or vaccine.

“Observational” studies collect information about people’s health during their normal care. This helps researchers learn more about specific health issues.

There are also other types of clinical research, such as trials with treatments that have already been approved.

Please note: Because of the diversity of identities and experiences among Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, and Asexual (LGBTQ+) people, and all sexual and gender minorities, you may have questions or concerns that are not covered by this brochure.

Why should clinical trials have diverse participants?

Treatments or vaccines may affect people of different races, ethnicities, ages, genders, or sexes in different ways. It’s important for everyone to be involved in clinical trials so we know how new treatments work and if they are safe for people from every community.

There is growing awareness in the healthcare community of the need for culturally competent and inclusive care. Culturally competent healthcare providers have specific training in the health needs of LGBTQ+ communities and in how to use culturally sensitive language, including pronoun usage.

The Healthcare Equality Index (HEI)

The HEI evaluates healthcare facilities' policies and practices related to the equity and inclusion of their LGBTQ+ patients, visitors, and employees. You can use this tool to find inclusive sites near you.

<https://www.hrc.org/resources/healthcare-equality-index>

Why have LGBTQ+ people not been represented in clinical trials?

Fear of discrimination

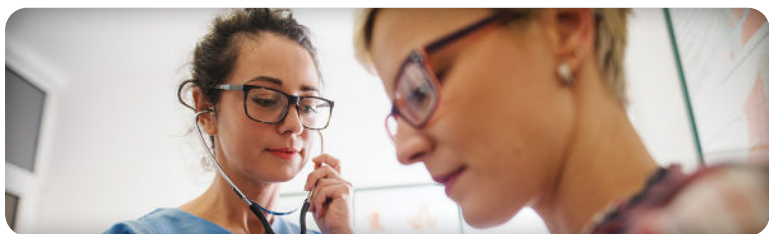
LGBTQ+ people experience unequal treatment, exclusion, homophobia, transphobia, and biphobia in healthcare settings. Recent examples include difficulty in accessing gender affirming care, gay men being denied from giving blood, restricted health insurance coverage for LGBTQ+ people, legislative efforts to strictly define sex based on reproductive organs at birth, and ongoing legislation that discriminates against trans people.

The research community is becoming more committed to being inclusive, but not all trials have appropriate in-take forms, inclusive requirements, staff training, or other equitable practices. This can prevent some LGBTQ+ people from participating in clinical trials.

Mistrust of clinical research and healthcare

Some people might mistrust doctors, researchers, or the healthcare system. Ongoing discriminatory legislation on LGBTQ+ healthcare have added to feelings of mistrust. Others might have concerns that research results might be used to negatively portray their community.

It's okay to ask whether a trial will be led by researchers and staff who are transgender, or gender diverse, with LGBTQ+ health competency. You can also ask the trial staff if research results will be shared after the trial.



Being in a trial is your choice. You can stop at any time and for any reason. The trial staff will help you do this safely.

Privacy concerns

The fear of being outed and other privacy concerns might prevent some people from participating in clinical research.

To protect participants, all clinical trials must follow federal laws that ensure your personal health information is kept private. Discuss any concerns with the trial staff and review the privacy and confidentiality protections in a trial's Informed Consent Form.

Keep in mind that not all trials will be inclusive and accommodating. But there are things you can do to help improve your experience.

- Seek out appropriate trial sites. This could mean looking for trials at sites that participate in the Healthcare Equality Index survey.
- Ask if the trial is led by researchers and staff with competency in LGBTQ+ health.
- Advocate for yourself. You can bring a family member, close friend, or ally to appointments for support.
- Participate in a patient advisory board. This lets researchers hear your perspective on concerns such as cultural competence and inclusion.

It may not be easy to do these things, but you deserve to have fair access to clinical trials.

How are trial participants protected?

Federal laws and guidelines protect the safety and privacy of clinical trial participants.

Clinical trials must be approved by an expert group called an institutional review board (IRB) that helps make sure the trial is fair, ethical, and as safe as possible.

What is Informed Consent?

Before you can participate, you must take part in a process called informed consent in which the trial staff fully inform you about a trial. When you sign an Informed Consent Form, you are acknowledging that you understand the trial and you agree to be in it.

When you sign an informed consent form, you are **not** signing any of your rights away.

What are some of the risks and benefits?

Possible risks

- The treatment in the trial may not help you.
- You may have side effects from the trial treatment.
- You may have frequent testing or blood draws.
- You may need to set aside time for participation.

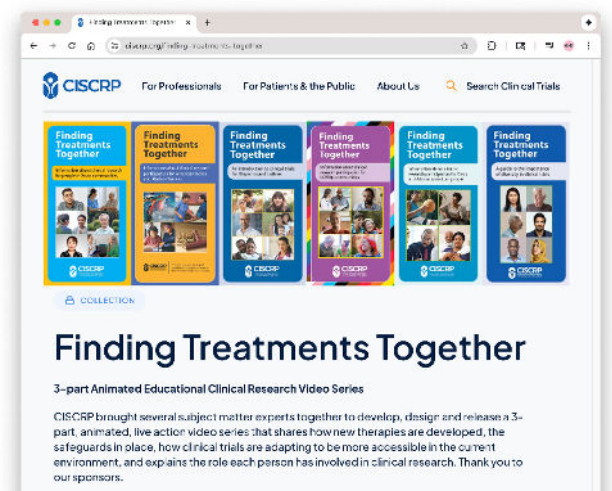
Possible benefits

- You may gain knowledge for yourself, your community, and the scientific community.
- You may have early access to advanced treatments for your condition.
- You may have access to treatment when no approved treatment exists.
- Your health will be watched by the trial doctors and nurses.

If you are thinking about participating in a clinical trial, be sure to talk with your doctor about the risks and benefits that may apply to you.

How can you find more information?

Patient advocacy groups may be able to tell you about clinical trials for your condition. If you would like to learn more about current clinical trials, call **1-877-MED-HERO**.



For more information from CISCRP's *Finding Treatments Together* series and for translations of this brochure, go to: findingtreatmentstogether.org



This brochure was developed together with members of LGBTQ+ communities and experts who work within those communities. It was also user-tested and reviewed with patients, the public, and health professionals. They all helped to make sure it is clear, non-biased, and culturally relevant.



CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process.

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.

Visit www.CISCRP.org or call toll free 1-877-633-4376