Finding Treatments Together

Information about clinical research participation for American Indian and Alaskan Natives

CISCRP
Center for Information & Study on Clinical Research Participation

This brochure was developed together with people and experts from American Indian communities.

American Indian and Alaskan Natives come from over 500 sovereign nations with distinct languages, ethnicities, cultures, and governments. Because of this wide diversity, you may have questions or concerns that are not covered by this brochure.

Why are clinical trials important?

Treatments or vaccines may affect people of different ages, sexes, races, or ethnicities in different ways. It's important that people from different American Indian and Alaskan Native communities are involved in clinical trials so we know how new treatments work and if they are safe for people from these communities.

Why should clinical trials have diverse participants?

Having diverse participants in clinical trials helps to ensure that treatments work for everyone. If you participate, you may help researchers find effective treatments for your community and future generations.

In the U.S., American Indians are underrepresented in clinical trials. In 2019, American Indian and Alaskan Natives made up less than 1% of the participants in National Institutes of Health (NIH) clinical trials. Because of this, scientific information on American Indian and Alaskan Natives is limited. So, clinical trial results may not tell us which treatments work best and are safest for American Indian and Alaskan Natives.

Why have American Indian and Alaskan Natives not been represented in clinical trials?

American Indian and Alaskan Natives have endured tragic abuses. Unethical research practices and medical misconduct have led to mistrust of the U.S. government, researchers, and healthcare professionals. From 1950 to 1976, researchers forced abortions and sterilizations upon thousands of American Indian women.

Havasupai Diabetes Project, Arizona State University

In the 1990s, Havasupai Tribe members gave consent to researchers to use their blood to study genetic links to diabetes. But, years later, researchers used these samples without consent from the tribe for studies on sensitive topics.

To provide more culturally competent care, the research community is continually making efforts to include American Indians as partners in clinical research. The NIH has worked with tribal nations to develop the Tribal Consultation Report on ethical practices for managing and sharing the data from its trials.

Cultural concerns

There might be concerns that clinical trial participation will conflict with cultural beliefs. For example, some people might follow traditional practices for handling blood or tissue samples. Others might wish to preserve tribal creation stories and traditional healing practices.

You have the right to find healthcare that respects your beliefs, values, and traditional healing practices. Also, there are opportunities to participate in health research that do not require giving blood or tissue samples.

You do not need to have tribal citizenship to participate in clinical research.

Difficulty accessing a trial site in person

It may be difficult to make trial visits if you live in a rural area or on a reservation. Some trial visits can take place over a phone or video call, or through local healthcare providers. You can discuss these possibilities with your healthcare provider.

Privacy concerns

To protect participants, all clinical trials must follow laws that ensure your personal health information is kept private. During the Informed Consent process, you can ask all the questions you need to understand a study before agreeing to participate. This includes questions about data privacy, confidentiality, and how your data and any blood or tissue samples will be used.

How are you protected if you participate?

Federal laws and guidelines protect the safety of clinical trial participants. Clinical trials must:

- follow laws and guidelines that make sure trials are ethical
- include an Informed Consent process
- be approved by an expert group called an institutional review board (IRB) that helps make sure the trial is fair and as safe as possible

What are the risks and benefits of participating in a clinical trial?

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 your 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 healthcare provider about the risks and benefits that may apply to you.

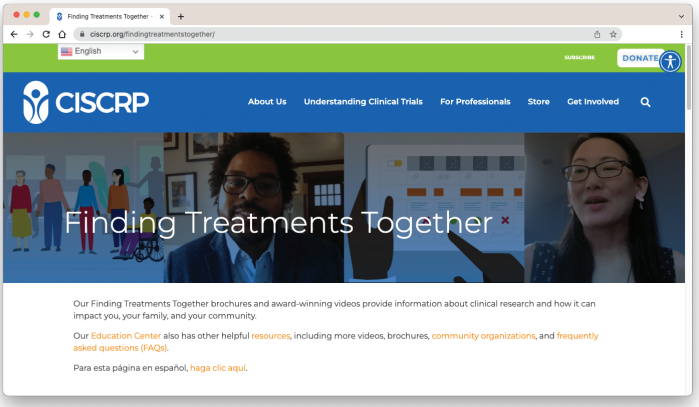
What are other ways you can get involved in clinical research?

- Participate in a clinical trial.
- Participate in an observational study that only collects health data.
- Join an IRB or patient group to share your perspectives with researchers.
- Discuss clinical research with elders, tribal leaders, traditional healers, or other members of your community.

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

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 on the topics in this brochure, the Tribal Consultation Report, and for translations of this brochure, go to: findingtreatmentstogether.org

CISCRP COMMUNITY COLLABORATION

This brochure was developed together with a diverse group of people and experts who have experience working with diverse communities.

It was also reviewed and tested with patients, the public, and health professionals. They all helped to make sure it is clear, non-biased, and culturally appropriate.

CISCRP

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

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