

# Clinical Trials, what are they?



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The purpose of this document is to answer questions that American Indian/Alaska Native cancer patients or caregivers may have about clinical trials.

This document is part of a series of information sheets developed by our University of Arizona NACP Outreach team. More information is available at: <https://nartc.fcm.arizona.edu/partnership-native-american-cancer-prevention-nacp>

## What is a Clinical Trial?

When an individual gets cancer, one of the options for their care and treatment is to receive medication. The medication can come in many different forms but before it can be prescribed or used, the medication must go through a lot of testing to make sure it is safe and that it works to help cancer patients.



As doctors and scientists are learning more about cancer, new medications and procedures are developed. The name for the testing of any new medication or procedure is **clinical trial**. A given clinical trial is often specific to a type of cancer and the trial occurs in steps called **phases**. A new medication or procedure must have good results before it can move to the next step, or phase (see figure). All medications must go through this process, not just the ones for cancer. Even the aspirin or Tylenol that you might take for a headache, muscle ache or fever have gone through this process.

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## What do I need to know?

If you or a family member are diagnosed with cancer and treatment is being undertaken, the doctor may ask if you would be interested to participate in a clinical trial. It is important to know several things about a clinical trial:

1. A clinical trial is a **research** study. The research is being done to answer specific questions about the medication or procedure. You will continue to receive the standard of care for your cancer. The research activities will be *in addition* to the treatment activities.
2. The research is being done to see if the medicine or procedure under study may or may not help in the care of *future* cancer patients. The main purpose is not to help you with your current cancer diagnosis, although it might. Sometimes people think the research is being done to help them, this is called **therapeutic misconception**.
3. It is important that you understand about what **your involvement** means in the research study. Here are a few things that you should make sure are okay with you. Make sure you understand exactly what will be involved.
  - a. *How much additional time will these research activities take?* This will be important if you are a long way from home and make special arrangements for your current treatment.
  - b. *Who will schedule the research activities on your behalf?* It will be important to let them know how far you must travel and the amount of time you have.
  - c. *Will they be drawing more blood? How much more and how frequently?* This is important if you must go to the Indian Health Service or a special lab to get your blood drawn.
  - d. *Will you need to have other tests done? Where and when?* It is important to know where else you may need to be going to get these tests done.
  - e. *Will you need to take additional medications?* How will that affect your current medications? It is important to understand the medications you are taking and what they are meant to help you with. Always make sure that your kidneys are strong enough to handle more medications.
  - f. *Will there be any upsets to your energy levels, sleep, eating, or physical activity?* Make sure to ask what kinds of side effects the medication is going to have on your body.
  - g. *What happens to your information after the study is over?* This is information about you and so it is important to know what will happen to it.
  - h. *Who will have access to your information?* It is important to make sure that all your information is protected, and this is your way of ensuring they are taking good care of your information.
  - i. *How will they stay in touch with you?* This is important because sometimes there may be limited data plans for your phone or the reception for your phone may not be as reliable. Making sure you understand what the follow-up steps include is important.
  - j. *What will happen if you change your mind and no longer want to participate?* For any study that you participate in, you will always have the choice to end your participation without loss of any of your existing current healthcare services. It is important to know that you can change your mind at any time.
  - k. *Will you get paid for participation? How will you get paid? What if you stop, will you get paid for the part that you completed?* Make sure you understand if you will get compensation. Your time and contributions are valuable and so you want to know if you will get money for your time.
4. The paperwork for a clinical trial is long and hard to understand. Make sure you ask for someone that you can talk to so you understand all the information, before you make a final decision. For some tribal languages, such as Navajo, there are **translators and interpreters** available to help you to understand.

## Explaining a clinical trial

A cancer clinical trial is a research study of a new medication or procedure. It is important to understand what phase you are being recruited for and what the purpose is of each phase. The higher the number of the phase, the further along the clinical trial is in determining the safety and efficacy of the new medication or procedure.

In **Phase 1**, researchers are gathering information to test if the new treatment is safe, discovering the right dosage amounts, and seeing what side effects may appear from the new treatment. In this phase, a small number of people (around 30 people) are enrolled.

In **Phase 2**, the new treatment is being tested to see how it affects the body and how it works with cancer. If a treatment shows it is working, it can continue to the next phase. Less than 100 people are enrolled at this phase.

In **Phase 3**, participants are assigned to different groups (sometimes called arms). In Phase 3, the new treatment is compared to the standard treatment and people are assigned to the different groups. The assignment into the different group can be randomized and blinded.

- *Randomized* – Participants are randomly assigned to a group, kind of like the toss of a coin. Heads you go to one group, tails, you go to the other group. One group is placed in the investigational group which consists of receiving the new treatment and the other group, called the control group, receives a standard treatment.
- *Blinded* – Participants may not be told which group they were randomly placed in.

Blinding falls into two different categories:

- *Single-blinded*: Participants are unaware of which group they are in and what intervention they are receiving until the trial is over.
- *Double-blinded*: Neither the participant nor researchers are unaware of what group the participant is in until the trial ends.

In Phase 3, more than 100 people are enrolled, and participants are usually part of the study for a couple of years. Phase 3 trials are intended to confirm the treatment process, that is, drug or procedure safety and efficacy.

In **Phase 4**, new treatments or procedures are approved through the Food and Drug Administration (FDA) and made accessible for use in treatment. Researchers continue to check for safety measures.

## Side Effects

Patients enrolled in clinical trials and receiving research medicine tend to have frequent follow-up appointments and are asked to be particularly aware of any side effects. It is important to inform your provider if the medicine is making you feel bad. Make sure to ask any questions you have and to let your provider or researcher know if you have any issues or comments.

## Clinicaltrials.gov

All clinical trials are required to register on a publicly available website, <https://clinicaltrials.gov>. There have been clinical trials specific to American Indians and Alaska Native people and you can find out more about them by entering keywords such as: “American Indian,” “Cancer,” “Native American,” “Tribal,” “Research,” “AI/AN,” “Alaska Native,” and “Indigenous.” At present, there is one Alaska Native Colon Cancer trial open.

## Resources

The **ClinicalTrials.gov** provides individuals easy access to obtain information on supported clinical trials. [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

The **Food and Drug Administration** provides information focusing on safety, efficacy, and security with medical products, drugs, and food to ensure health improvement. [www.fda.gov](http://www.fda.gov)

The **HIPAA Privacy Rule** provides privacy and protection of health information. [www.hhs.gov](http://www.hhs.gov)

The **National Cancer Institute (NCI)** provides and supports cancer research information across the nation to help individuals live healthier lives. [www.cancer.gov](http://www.cancer.gov)

The **National Institutes of Health (NIH)** provides information on new ways to prevent, detect, or treat disease with clinical trials. [www.nih.gov](http://www.nih.gov)

The **Office for Human Research Protections (OHRP)** provides basic information about research and research participation to help with informed participatory decisions with research. [www.hhs.gov](http://www.hhs.gov)

## Reading Suggestions

NIH clinical trials and you. (2017). National Institutes of Health. Retrieved September 22, 2020, from <https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics>

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