

Native American Cancer Research (NACR) Corporation: “Clinical Trials Education for Native Americans”



Fact Sheet



- 🍵 Clinical trials are usually conducted with white, well-educated and insured people, but rarely with Natives.
- 🍵 Learning more about clinical trials can help you make informed decisions about taking part in a clinical trial
- 🍵 “Informed decision” means you understand the possible pros and cons of taking part. Then you can make your choice based on what is right for you
- 🍵 Now you know. Now you can.

What is a “clinical trial”?

- 🍵 A study designed to answer a specific scientific question
 - ⊕ conducted with people
 - ⊕ designed to find better ways to diagnose, prevent and treat cancer
- 🍵 Clinical Trials are one stage of a thorough research process
- 🍵 Clinical Trials can look at:
 - ⊕ Methods of prevention, screening, diagnosis, treatment, and quality-of-life/supportive care (side effects)
 - ⊕ Genetics (how genes can influence therapies)
 - ⊕ New combinations of treatments already in use
 - ⊕ New ways to provide treatments
- 🍵 Follow “protocols” (a recipe for conducting the trial), which are reviewed by Institutional Review Boards (IRBs)
- 🍵 IRBs review and approve the protocol to make sure the study is conducted properly, fairly, ethically, and participants are not harmed
- 🍵 Have eligibility criteria
- 🍵 Require “informed consent”



“Native people need to take charge of your own health care.”

Mankiller, 2005



Wilma Mankiller

Former Principal Chief, Cherokee Nation of Oklahoma; participant in clinical trials for 2 types of cancer; Nov 1945 – April 2010

Why is it important for Natives to get information about clinical trials?

- 🍵 Clinical trials provide high-quality, up-to-date care for today’s cancer patients.
- 🍵 According to Native Survivors’ Network findings, Native patients are not receiving the best care available.
- 🍵 Taking part in a clinical trial may increase your access to high quality care
- 🍵 Natives may respond differently to a specific clinical treatment
- 🍵 The provider may track your side effects more closely on a clinical trial
- 🍵 The provider may follow up changes in your cancer more closely on a clinical trial
- 🍵 If Natives are not in the trials, we don’t know if there are some unique problems for Native patients.



What are the purposes of clinical trials?

- 🍲 Provide high-quality, up-to-date care for today's cancer patients.
- 🍲 Identify the best "standard" treatment
- 🍲 Identify effective, new approaches to cancer treatment and care
- 🍲 Improve cancer survivorship and quality of life
- 🍲 Reduce side effects
- 🍲 Improve management of side effects
- 🍲 Gain greater comfort in cases where the cancer itself cannot be cured.
- 🍲 Reduce the incidence of cancer
- 🍲 Delay the development of cancer
- 🍲 Reduce cancer-related death and disability



Maxine Brings Him Back Janis
Oglala Lakota
Dx cervix 1978; breast 2002
participant in clinical trials

Right to Choose

- 🍲 This doesn't mean that all trials are "right" for you
- 🍲 It does mean that you should be provided information about existing trials
- 🍲 Once you have information, you can make an informed decision about whether or not to take part in a specific trial.
- 🍲 Even if you choose to take part you still need to meet the "eligibility requirements"

Why are clinical trials important?

- 🍲 There are more than 100 different types of cancer
- 🍲 "Cures" only exist for a small proportion of these cancers
- 🍲 No single "cure" is effective for all types of cancer.
- 🍲 Clinical trials are how new cures are found
- 🍲 Clinical trials are how science learns to "control" cancer
 - ⊕ Cancer is becoming a "chronic" disease, like diabetes
 - ⊕ Many patients will not die from cancer
 - ⊕ You may live many years with cancer and not die from cancer
- 🍲 Clinical trials have led to a cure for:
 - ⊕ Childhood leukemia
 - ⊕ Testicular cancer
- 🍲 Clinical trials identify the best treatment; that becomes the standard of care.
- 🍲 The "standard care" is compared with another type of treatment that looks like it may be better!
- 🍲 By being in a trial, even if you are in the "control" group on a treatment trial, you will receive at least "standard care" (no sugar pills for NIH trials)



"Although in many tribal communities, we resist the notion of participating in clinical trials when we have been diagnosed with cancer, I think that if we are going address the rising cancer disparities in our communities, we do have to participate in clinical trials. As a Native person, it is not for me. Remember, we are doing it for those who follow us. We look to 7 Generations ahead and I think this the way we give back; protecting the 7 Generations to come." Maxine Brings Him Back Janis 6/2011

Participating in a clinical trial may:

- 📦 Improve cancer survivorship and quality of life
- 📦 Result in fewer side effects from treatment
- 📦 Result in better management for your side effects
- 📦 Provide better comfort in cases where the cancer cannot be cured
- 📦 Identify effective, new approaches to cancer treatment, especially when no effective treatments exist
- 📦 Clinical trial studies improve patient outcomes:
 - ⊕ Reduce cancer-related disabilities and deaths
 - ⊕ Reduce the incidence of cancer
 - ⊕ Delay the growth of cancer
 - ⊕ Increase survival from cancer
 - ⊕ Lower recurrence for many cancers



What information is collected during and after a clinical trials?

- 📦 The type of information you will need to take part in the study such as
 - ⊕ Keep a study diary
 - ⊕ Eat special foods
 - ⊕ Record information to tell your provider

During the clinical trial, info, such as:

- 📦 Side effects (upset stomach, headaches)
- 📦 Blood counts (white and red cells, liver)
- 📦 Appearances (scarring, discoloration)
- 📦 How well the cancer responds to the treatment.

After the clinical trial is over, info, such as:

- 📦 Overall quality of life
- 📦 Delayed side effects (unable to get pregnant)
- 📦 Recurrence or spread of the cancer
- 📦 Appropriate follow-up appointments
 - ⊕ Any new medical conditions diagnosed since treatment completed?
- 📦 Appearance (cosmetic outcome, like a lot of scarring on the breast(s) following radiation)

What are the types of clinical trials?

- 📦 Prevention Trials identify methods that prevent cancer; includes studies of:
 - ⊕ Medicines
 - ⊕ Vitamins
 - ⊕ Minerals
 - ⊕ Other supplements
 - ⊕ Exercise
 - ⊕ Diet
 - ⊕ Daily behaviors
- 📦 Early Detection test ways of finding cancer early before symptoms appear; includes studies of:
 - ⊕ X-rays
 - ⊕ Blood tests
 - ⊕ Diagnostic machines
 - ⊕ Physical exams
- 📦 Treatment Trials find more effective treatments for people who have cancer, includes studies of:
 - ⊕ Compares a “standard” treatment with a “new” treatment.
 - ✦ New therapy
 - ✦ New way of using a known treatment (like Thalidomide)
- 📦 Quality of life trials find better ways to manage treatment and cancer-related side effects
 - ⊕ Treat side effects
 - ⊕ Impact of therapies on the patient and family
 - ⊕ Identifies long-term effects of cancer and treatment

For information about specific clinical trials, go to:

<https://clinicaltrials.gov/>

This is a database of privately and publicly funded clinical studies conducted around the world.



What concerns do Natives have about clinical trials? Many Natives believe that:

- Most clinical trials are done on Natives rather than other minorities. **REALITY:** Natives are rarely included in clinical trials.
- Natives are used like guinea pigs. **REALITY:** Guinea pigs don't have a choice about taking part in a study, but we do.
- Natives are the frequent victims of experiments by the US government. **REALITY:** This was true (American Indian sterilization), but not common today.
- Natives are over-studied with little good going back to the local community. **REALITY:** Few studies result in increased / improved services for the local community but the trial may be beneficial *to you* ... so informed choice is important.



Patti King, Gila River, AZ

Clinical Trials - our own doctors don't think Native People will be interested

What are tribal / Native barriers to taking part in clinical trials?

- Patients not informed of the availability of trials
- Need approvals from the Tribal / IHS Institutional Review Board and the Tribal Research Committee for a trial offered by the tribal clinic
- Some Tribal Research Committees forbid taking part due to:
 - Lack of resources for cancer care if the tribal member has to withdraw from the clinical trial (but the "experimental part" is paid for by the trial)
 - Inability to use "participatory" research design that includes tribal Nation as an equal partner in all decisions
 - Distrust of the research "agency"
- The Community Health Representative (CHR) unable to give rides to and from the clinic for all of the required appointments
- Tribal clinic unable to help with clinical trial side effects or co-morbidities (diabetes)

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For more information, contact

Native American Cancer Research Corporation (NACR)
3022 South Nova Road
Pine, CO 80470-7830
Phone: 303-838-9359
<http://www.NatAmCancer.org>