


Clinical Trials Education for Native Americans (CTENA)




Clinical Trials Education for Native Americans

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Introduction

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What is a Clinical Trial?

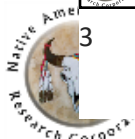
- A study designed to answer a specific scientific question
- That is conducted with people
- And designed to find better ways to diagnose, prevent and treat cancer
- Clinical Trials are one stage of a thorough research process



Maxine Brings Him Back Janis
Dx cervix 1978
Dx Breast 2002

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Are American Indians and Alaska Natives over-enrolled in Clinical Trials?


- No
- Most participants are whites who are well-educated and have private health insurance
- Most Natives who take part ask for information about clinical trial opportunities
- Or select hospitals, such as Rapid City Regional Hospital, practice respectful communication between patients and providers (Dr. Daniel Peterit) to discuss all aspects of the clinical trial so the patient can make an informed choice

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What are clinical trials (cont.)


- Research studies that evaluate promising new therapies and answer scientific questions.
- Clinical Trials can look at:
 - Methods of prevention, screening, diagnosis, treatment, and quality-of-life/supportive care (side effects)
 - Genetics (i.e., how genes can influence therapies)
 - New combinations of drugs already in existence
 - New ways to provide treatments

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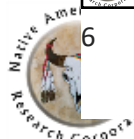
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Clinical Trials

- Follow “protocols” (a recipe for conducting the trial), which are reviewed by Institutional Review Boards (IRBs)
- Have IRBs review and approve the protocol in order to make sure the study is conducted properly, fairly, ethically, and participants are not harmed
- Have eligibility criteria
- Have participants go through a process called “informed consent”

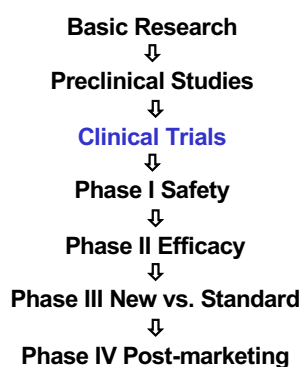
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Stages of the Clinical Trials Process:



Clinical Trial Phases

- Phase I –
 - ⊕ Determines amount of a medicine (dose) that is safe, how it should be given, and how often
 - ⊕ Typically a small number of patients involved
- Phase II
 - ⊕ Studies safety and effectiveness of a medicine
 - ⊕ Typically fewer than 100 patients



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Clinical Trial Phases

- Phase III
 - ⊕ Studies difference between the new medicine/therapy and the standard therapy
 - ⊕ Participants randomly assigned to either receive standard or new therapy
 - ⊕ Typically involves large numbers of patients throughout the country or across the world




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Clinical Trial Phases

- Phase IV (post-marketing)
 - Conducted to evaluate the long-term safety and effectiveness
 - Usually after FDA has approved therapy for standard use
 - Can involve several 100 to several 1000 patients

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Synopsis

- Patient talks with "Advocate" / "Navigator"
- Patient tells Advocate of his/her concerns (e.g., dx w/ colon cancer; family member recently diagnosed)
- Advocate / Navigator determines which "type" (category) of clinical trial may be relevant

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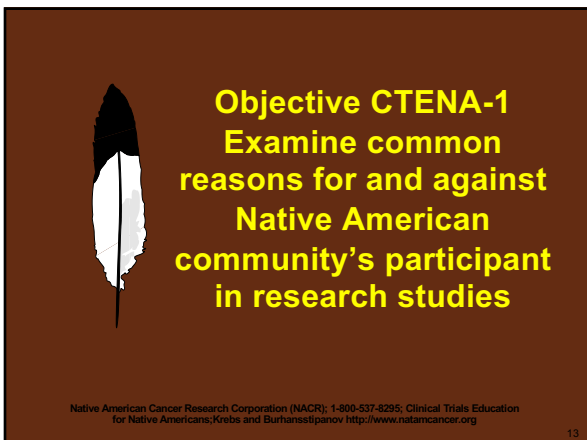
Synopsis

- Go on web or call 1-800-4-CANCER and ask
 - "I am looking for a "treatment" trial for colon cancer"
 - For a patient living in "xxx" geographic area
 - This patient is interested in a Phase "xxx" trial

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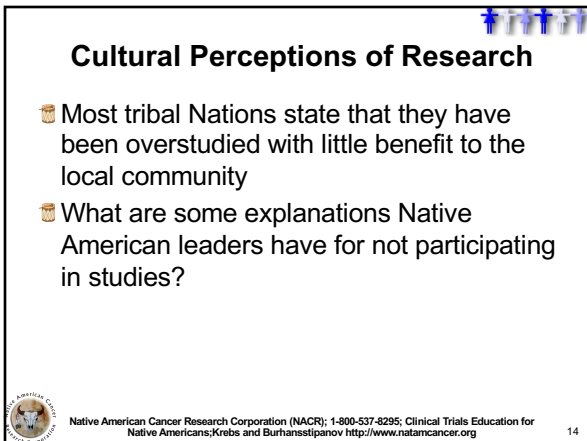


Objective CTENA-1
Examine common reasons for and against Native American community's participant in research studies

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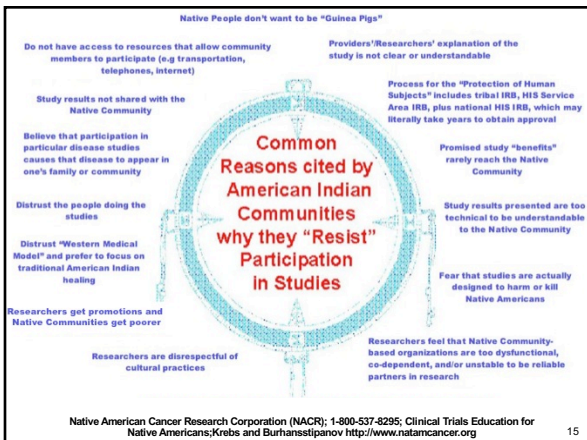
Cultural Perceptions of Research

- Most tribal Nations state that they have been overstudied with little benefit to the local community
- What are some explanations Native American leaders have for not participating in studies?

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Common Reasons cited by American Indian Communities why they "Resist" Participation in Studies

- Native People don't want to be "Guinea Pigs"
- Do not have access to resources that allow community members to participate (e.g. transportation, telephones, internet)
- Providers/Researchers' explanation of the study is not clear or understandable
- Study results not shared with the Native Community
- Process for the "Protection of Human Subjects" includes tribal IRB, HIS Service Area IRB, plus national HHS IRB, which may literally take years to obtain approval
- Believe that participation in particular disease studies causes that disease to appear in one's family or community
- Promised study "benefits" rarely reach the Native Community
- Distrust the people doing the studies
- Study results presented are too technical to be understandable to the Native Community
- Distrust "Western Medical Model" and prefer to focus on traditional American Indian healing
- Fear that studies are actually designed to harm or kill Native Americans
- Researchers get promotions and Native Communities get poorer
- Researchers are disrespectful of cultural practices
- Researchers feel that Native Community-based organizations are too dysfunctional, co-dependent, and/or unstable to be reliable partners in research

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Native American Cancer Care

- Native Americans are not receiving quality cancer care in comparison with other racial groups
- Taylor-Wilson's study of AZ / NM breast cancer data (NCI / IHS)
 - More than 6 months from diagnosis to beginning of cancer treatment
- Same findings from "Native American Cancer Education for Survivors"



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Unique Issues Facing American Indians and Alaska Natives in Getting Breast Cancer Care

- "Cancer" not discussed within many Native cultures
- "Prevention" and "early detection" are unusual concepts within the cultures
- Cancer has "cultural" interpretations that vary among Tribal Nations



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Objective CTENA-2
Describe the
importance of
including Native
Americans in clinical
trials.

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Native American Cancer Research
<http://www.NatAmCancer.org>;

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QUESTION: Do more or fewer Native people take part in clinical trial studies than other racial / ethnic groups?

☞ Very few

- ☞ Why or why not?
- ☞ Many Native Americans believe that we are the frequent victims of experimentation by the U.S. government
- ☞ Guinea pigs



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Why important?

☞ Most clinical trials participants are:

- ☞ Well educated (e.g., college degree)
- ☞ High socioeconomic "group"
- ☞ White (Caucasian)

☞ Most have private health insurance and are more likely to be referred to a clinical trial than are Natives

- ☞ Of whom only 1/3 have private insurance
- ☞ Some have IHS (which is not insurance)



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QUESTION: How could clinical trials be more inclusive of Natives?

☞ Allow variations in the protocols

☞ The STAR included collection of genetic specimens

- ☞ Some tribes had sanctions against allowing for the collection of genetic specimens, like Cherokee Nation
- ☞ NIH representative met with the Tribal Nation and negotiated participation excluding genetic specimens




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More Reasons / Explanations

- 📋 Tribal sanctions based on previous experiences in research
- 📋 Not informed of the availability of trials for which they are eligible
- 📋 Need Tribal / IHS IRB approval if the trial is in tribal clinic




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Why is it important to have an option /choice about taking part in clinical trials?

- 📋 More than half of 700+ Natives cancer survivors enrolled in "Native American Cancer Education for Survivors" program had difficulty accessing cancer care
 - ⊕ The patients who take part in clinical trials may have increased access to timely and high quality care
- 📋 Natives may respond differently to a specific clinical protocol or drug




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Why important (cont.)

- 📋 Cultural or poverty issues may affect the recruitment, retention and compliance with the clinical trial protocols
 - ⊕ More than 1/4 of Native survivors in the "Native American Cancer Education for Survivors" program travel more than 300 miles one-way to access cancer care.
 - ⊕ Clinical trials may be able to pay for gasoline or hotel stays



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What if the clinical trial required the participant to have a medical check up every week over a 1 month period of time?

- Most Natives who live long distances from the clinical setting are likely to drop out
- Or the clinic can identify a variation in the protocol that would allow the patient an alternative way to participate

QUESTION:What if that "month" overlapped with an annual tribal ceremony or holiday (Sun Dance? Green Corn)?



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Why Important?

Why is it important that Native Americans have a choice about participating or not participating in clinical trials?

- Increase access to high quality care
- Natives may respond differently to a specific clinical regimen



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Why important? (cont.)

- Increase access to high quality care
- Natives may respond differently to a specific clinical regimen



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QUESTION: What if the clinical trial required eating certain nutritious foods daily?

- ☞ But the ceremony required several days of fasting?
- ☞ What if local tribal cultural practices include taking herbal treatments recommended by the traditional Indian healer?
 - ⊕ But those herbs interact / interfere with cancer treatment drugs?



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Poverty and Transportation

- ☞ May affect "compliance"
 - ⊕ "5 a day" in a 'prevention' trial for families who cannot afford fresh fruits and vegetables
 - ⊕ Women's Health Initiative that required clinical visits every two weeks -- but Native people have limited access to transportation to and from the clinic and the reservation =
 - ✓ Natives moved to control group



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For Example: Breast Cancer Prevention Trial

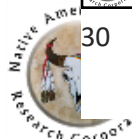
- ☞ 13,000 women and included use of tamoxifen
 - ⊕ Only 34 (out of 13,000) recruited were American Indian
 - ✓ And only 27 completed the study
- ☞ QUESTION: Did they quit because they had a lot of side effects from the drug?
 - ⊕ Did they quit because they were unable to make it to all of the required health check-ups?



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Why Important? (cont.)


- Cultural issues may affect the recruitment, retention and conduct of a trial
- What if the clinical trial required the participant to have a medical check up every week over a 1 month period of time?
- What if that “month” overlapped with annual tribal ceremony or holiday?
- Sun Dance?
- Green Corn Ceremony?

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Why Important?


- What if the clinical trial required eating certain nutritious foods daily?
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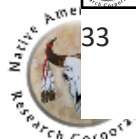
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Why Important?

- Poverty and other economic barriers may affect “compliance”
- ... “5 a day” in a ‘prevention’ trial for families who cannot afford fresh fruits and vegetable
- ... Women’s Health Initiative that required clinical visits every two weeks -- but Native people have limited access to transportation to and from the clinic and the reservation

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QUESTION: How have clinical trials influenced cancer care?


- Treatments validated by clinical trials have improved patient outcomes
- Better survival from cancer
- Lower recurrence rates for many cancers
- New approaches to treat previously untreatable cancers
- Fewer side effects, better quality of life

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Objective CTENA-3


State the purpose and importance of clinical trials.

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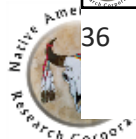
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Purpose

- Test new methods of preventing and controlling cancer.
- Goal is to find better ways to prevent and treat cancer and to help cancer patients, their families and loved ones.
- And to assess the effectiveness of new treatments or devices.

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Common Questions from Native patients


- Why does the government have to do cancer experiments?
- Why don't they just let the public have the new medicines?
- Don't animal studies provide all of the information cancer doctors really need for cancer treatment?

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Common Questions from Native patients


- "Isn't it true that the doctors / governments have access to a cure for cancer, but they just don't want to lose the income they get from cancer treatment?"
 - Common accusation ... but not true
 - A large number of cancer researchers have family members who have passed on from cancer

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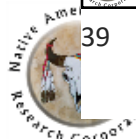
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Cancer cures


- Some cancers have successful cures ... as long as they are found in early stages of development!
 - Childhood leukemia
 - Cancer of the cervix
- The cures "occurred" as a result of clinical trials research
- "Cures" exist for a small proportion of the 100 different types of cancer

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Cancer cures

- 🗨️ No single “cure” is effective for all types of cancer.
- 🗨️ “Cancer trials” are how the cures are found for specific types of cancer.
- 🗨️ Most providers who work in cancer care have family members or loved ones who have been diagnosed with cancer.
- 🗨️ Providers are as anxious as anyone else for cures to all cancers to be found.

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Importance of cancer care trials

- 🗨️ To provide high-quality, up-to-date care for today's cancer patients.
 - 🔄 According to Native Survivors' Network “preliminary findings”, our patients currently are not receiving the best care available ...
- 🗨️ CT identify the best “standard” treatment

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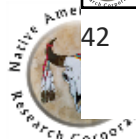


Importance of cancer care trials

- 🗨️ In most trials, the “state-of-the-art” care is compared with another type of treatment or care that looks like it may be even better!
- 🗨️ By Indian people being in the trial, they may have the chance to get “state-of-the-art” care.
- 🗨️ Improve cancer survivorship and quality of life

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Importance of cancer care trials


- Natives have the poorest survival from cancer in comparison with other races and ethnicities
- Find fewer side effects from treatment
- Greater comfort in cases where the cancer itself cannot be treated
- Know that they are helping others who experience cancer in the future

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Importance of cancer care trials


- CT seek to reduce side effects of treatment
- Most common side effect of the cancer experience is
 - Fatigue, feeling tired ... not having as
 - Unmanaged pain
 - Depression
 - Loss / reduction in sexual feelings

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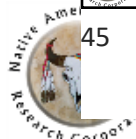
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Importance of cancer care trials

- To identify effective, new approaches to cancers (i.e., no widely effective treatments exist)
- Few Native cancer patients are in these types of trials
- To allow medically underserved, un/under-insured cancer patients access to state-of-the-art treatments

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Importance of cancer care trials


- By going through a National Cancer Institute clinical trial, the uninsured Native patient may receive better cancer care
- To reduce the incidence of cancer
- To delay its onset
- To reduce cancer-related death and disability (e.g., prevention and/or control trials).

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Importance of cancer care trials


- Some types of cancer trials are for people who do not have cancer
- Some trials are for people who are 'high risk'.
- "High risk" does NOT mean that you will get cancer.

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Why CT Important?

- For selected studies, participants may get more careful and regular medical attention
- Thus general health problems may be found early
- Like diabetes-related problems
- Health care standards and quality treatment are decided by these trials

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Why Important?

- ⊕ If Native Americans are left out of these trials ...
 - ✓ They have no influence on such standards
- ⊕ Unique features or barriers related to Indian health care continue to go unrecognized by health care professionals and agencies
 - ✓ Like “contracted health services”



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The Right to Choose

- 🗨 This doesn't mean that all trials are “appropriate” for Natives to take part in ...
- 🗨 But it does mean that Natives should be provided information about existing trials



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The Right to Choose

- ⊕ So they can make an informed decision about whether or not to participate in a specific trial.
 - ✓ Ethics of the patient's “autonomy”
 - ✓ Ethics of patient “justice”



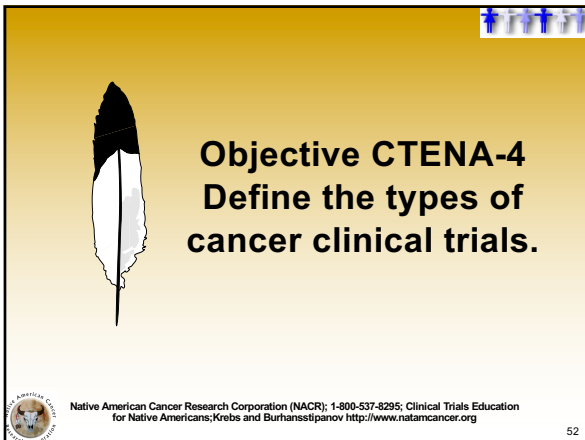
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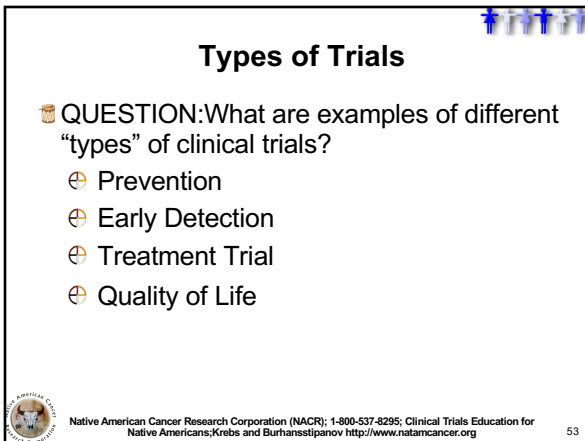
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Objective CTENA-4
Define the types of
cancer clinical trials.

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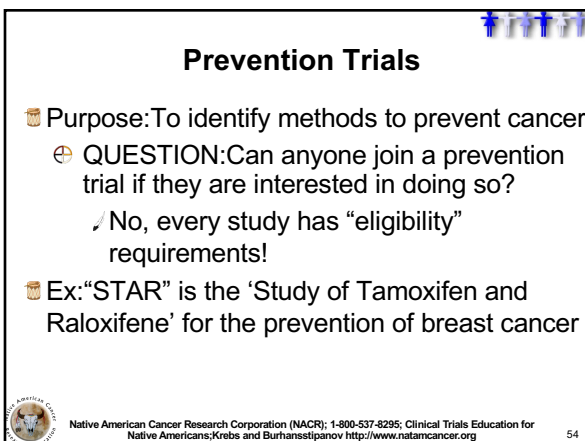
Types of Trials

QUESTION: What are examples of different "types" of clinical trials?

- ⊕ Prevention
- ⊕ Early Detection
- ⊕ Treatment Trial
- ⊕ Quality of Life

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Prevention Trials

Purpose: To identify methods to prevent cancer

QUESTION: Can anyone join a prevention trial if they are interested in doing so?

✓ No, every study has "eligibility" requirements!

Ex: "STAR" is the 'Study of Tamoxifen and Raloxifene' for the prevention of breast cancer

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Prevention Trials

QUESTION: What are examples of eligibility criteria for the STAR Trial?

- ⊕ 35 years old or older
- ⊕ Post menopausal (no more moons)
- ⊕ No hormone therapy for at least 3 months
- ⊕ No personal problems with blood clots


 Native American Cancer Research Corporation (NACR); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org> 55

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Prevention Trials

Because these studies are on ways to “prevent” cancer, what is a necessary characteristic of a participant?

- ⊕ People do not have cancer
- ⊕ People may have a family member with cancer


 Native American Cancer Research Corporation (NACR); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org> 56

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Prevention Trials

Many different “forms” of prevention are being studied that may lower the risks of certain cancers


- ⊕ Medicines
- ⊕ Vitamins
- ⊕ Minerals
- ⊕ Other supplements
- ⊕ Exercise
- ⊕ Dietary changes
- ⊕ Life style changes

 Native American Cancer Research Corporation (NACR); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org> 57

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Clinical Trials Education for Native Americans (CTENA)



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Early Detection Trials

Purpose: To test ways of finding cancer early before symptoms appear.

QUESTION: Why do we need new methods of early detection?

- ⊕ Assess methods of screening for cancer
 - ✓ Includes x-rays
 - ✓ Diagnostic tests
 - ✓ Blood tests
 - ✓ Physical exam

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Early Detection Trials

Example: clinical trial of annual chest x-rays and spiral CT scans in patients at high-risk for lung cancer.

⊕ QUESTION: For whom is this trial?

- ✓ People who habitually smoke

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Treatment Trials

Purpose: To find more effective treatments for cancer.

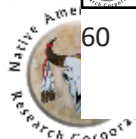
- ⊕ For people who have cancer
- ⊕ Compares a “standard” treatment with a “new” treatment
- ⊕ Finds new therapies
- ⊕ A new way of using a known treatment

Thalidomide as a cancer treatment?


Shown to be effective:

- prostate...multiple myeloma

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Treatment Trials

- ⊕ Thalidomide as a cancer treatment?
 - ✓ Shown to be effective:
 - ✓ Prostate...multiple myeloma




Native American Cancer Research Corporation (NACR); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>

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Quality of Life Trials

- 📖 Purpose: To find better ways to manage treatment and cancer-related side effects
- 📖 Starts at onset of treatment and continues
 - ⊕ Example: evaluate the efficacy of acupressure in reducing nausea and vomiting on the day of treatment and 1-4 days following treatment.
 - ⊕ Protocol I.D. URCC-U3997, NCI-V99-1528




Native American Cancer Research Corporation (NACR); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>

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Quality of Life Trials

- 📖 Includes “quality of life” studies
- 📖 Looking at what impact cancer therapies have on the patient and the family.
- 📖 Most trials now include evaluation of quality of life.
- 📖 regardless of disease outcome



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Quality of Life Trials

- Includes survivor trials
- Purpose: To identify the long-term effects of cancer and its treatment. . . and then to test strategies to minimize these effects in the cancer survivor.

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Objective CTENA-5

Explain phases of cancer clinical trials.


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Phases:Introduction

- Trials are categorized into different “phases” of the research process
- Taken collectively...Phases I through IV illustrate “translational” research ...
- “from the bench to the bedside”

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Clinical Trials Education for Native Americans (CTENA)

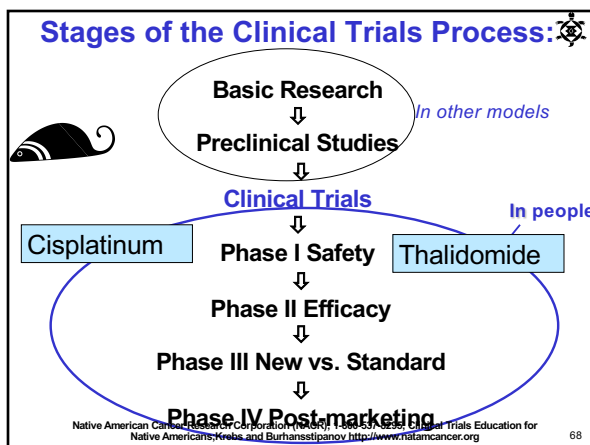
Phases: Introduction

QUESTION: Why is it important for a cancer patient to know the “phase” of a clinical trial?

Creates realistic expectations of who is likely to “benefit” and why ...

Native American Cancer Research Corporation (NACRC); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>

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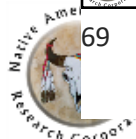
Phase I: Safety

QUESTION: What does “pre-clinical” mean?

- Prior to implementation in humans
 - Molecular
 - Computers
 - animals
- More recently done with computer models and virtual humans

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Phase I: Safety


- Determine the best and safest way to give a new treatment
- To determine the maximum tolerated dose for one or more schedules of drug administration

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Phase I: Safety


- In cancer “treatment” ...
 - Patients have “advanced” disease
 - Patients have not been helped by other known treatments
 - No better treatment to offer

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Phase I: Safety

- Patients are not expected to personally benefit
- The trial determines dosage, side effects
- Only about 10 people are enrolled

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Phase I: Safety

🗣️ **QUESTION:**What does “toxicity” mean for humans?

- ⊕ Excessive toxicity = trial will be stopped
- ✓ Some side effects do not occur in animals ... i.e., humans need to be involved.e.g., dogs do not lose their hair from adriamycin

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Phase II: Efficacy

🗣️ Find out how well a new drug works in a specified tumor type

🗣️ Small number of participants (e.g., 25)

🗣️ Patients have been (1) untreated; or (2) have shown little to no response to previous drug treatment; or (3) have relapsed after standard treatment

 Native American Cancer Research Corporation (NACRC); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org> 74


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Phase II: Efficacy

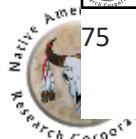
🗣️ Need to see at least 20% improvement to proceed to the next phase

🗣️ Tumor = smaller

🗣️ People “feel” better

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Phase II: Efficacy


- Example: SW American Indian woman on a Phase II bladder cancer trial
- "Standard" treatment was not working
- i.e., tumor showed no improvement

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Phase II: Efficacy


- Patient's prognosis = not good
- Phase II treatment = significant side effects
- Phase II Treatment = tumor shrunk!!
- She stayed on the trial

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Phase III: New vs. Standard


- New treatment compared with standard treatment
- same stage of cancer
- same type of cancer
- Large numbers of participants
- 100 to 1,000's of people

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Phase III: New vs. Standard

- 📋 Patient followed for treatment effects for several years
- 📋 Standardized medical check-ups while under-going the new treatment




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Phase III: New vs. Standard

- 📋 New treatment compared with standard treatment
- 📋 Looks at responsesurvival
- 📋 Toxicityimpact on quality of life



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Phase III: New vs. Standard

Patients randomly assigned to standard treatment or to new treatment

No “sugar pill” / placebo group were identified in NCI “treatment trials” (2001)

“Cure” is the goal!!



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Phase III: New vs. Standard


- Patients randomly assigned to standard treatment or to new treatment
- No “sugar pill” / placebo group were identified in NCI “treatment trials” (2001)
- “Cure” is the goal!!

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Phase IV: Post-FDA Approval

- Trial designed to answer additional questions since receiving the original FDA approval

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Objective CTENA-6
Examine selected and common Native American myths and beliefs related to cancer clinical trials.


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Clinical Trials Education for Native Americans (CTENA)




 There are many ideas about how and why research is done within Native American communities.


 Many Natives have valid reasons to be suspicious of research.





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 One needs to be able to distinguish between misinformation and fact to make an informed choice.


 We are going to play a short game to address some of the beliefs Natives have raised about research and clinical trials in Indian Country.




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The Rules

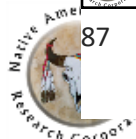


1. Please form groups of approximately five people each.
2. Each group will be given a stack of index cards containing clinical trials “facts” or “myths.” The cards are passed out so that each group member has at least one card.




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Clinical Trials Education for Native Americans (CTENA)



The Rules


3. Ask one person within each group to be in charge of the “key card.” The “key card” contains the answers to the clinical trials’ statements.

 **NOTE:** The person who “holds” the “key card” also participates in the game as a regular player.





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4. One person in each group reads the statement on the index card.

 The group then discusses the statement and must decide whether it is fact or fallacy.



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The Rules

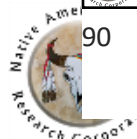
5. The individual who has the “key card” then checks the card number and answer to see whether the group answered correctly.

6. If the group is correct, proceed to another card and follow the same procedure.




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Clinical Trials Education for Native Americans (CTENA)



The Rules


7. If the group was incorrect, write the card number on a separate piece of paper.

8. If the group was correct, but some members of the group would like to debate or discuss the statement further, the card number is listed on a separate piece of paper.




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The Rules

NOTE: Only the card numbers listed on the separate sheet of paper will be discussed with the entire group.




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Please take the next 15 minutes to play the game ...



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Clinical Trials Education for Native Americans (CTENA)




1. Most clinical trials research is done with Native Americans. *Myth*

👤 Most are upper middle class, well-educated Caucasians




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2. Native Americans almost always have the costs of cancer trials paid for by their tribe. *Myth*

👤 Tribal health programs are too under-funded to support additional costs related to clinical trials participation.



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Myths or Facts

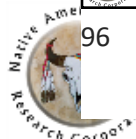
3. "Sugar pills" (placebos) are frequently used in a cancer clinical treatment trial. *Myth*

👤 Cancer treatment trials compare "standard" care with a "new" treatment ... rarely placebos



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Clinical Trials Education for Native Americans (CTENA)

Myths or Facts

4. If a Native is interested in taking part in a clinical trial, they are automatically “eligible” to enroll because they are a minority. *Myth*

👤 All clinical trials participants must meet scientific eligibility criteria


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Myths or Facts

5. Research safeguards are currently in place to reduce the likelihood that American Indians are used in research without their informed consent. *Fact*

👤 This is true for federally supported studies, but not so for privately funded studies.


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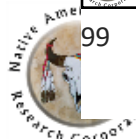
Myths or Facts

6. Clinical trials are designed to make money for health care providers. *Myth*


👤 Providers rarely earn any money for referring participants to clinical trials

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Clinical Trials Education for Native Americans (CTENA)




Myths or Facts


7. Only ethically and scientifically based clinical trials are listed on the Internet.

Myth

 Anyone can post information on the Internet -- much misinformation is posted there.


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Myths or Facts

8. There is currently an effort for tribal communities to have a voice in how clinical trials protocols are develop *Myth*

 Scientific protocols are determined by the federal government and academic research institutions with little to no input from tribal nations.

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Myths or Facts

9. Each Native American participant on a clinical trial is cared for by a health care provider who is familiar with our cultures.

Myth


 Most providers receive little to no accurate education about the diverse tribal cultures.

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Myths or Facts

10. Participants in clinical trials may have some out-of-pocket costs paid for by the health care facility. **Fact**


 Many clinical trials have programs in place to help offset costs such as parking fees or bus tolls, but may or may not include medication costs.



Native American Cancer Research Corporation (NACRC); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>


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Myths or Facts

11. Native People are basically “guinea pigs” in clinical trials **Myth**

 Guinea pigs do not have a choice.


 The potential participant does!



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Myths or Facts

12. Some federally supported clinical trials in the last decade were designed to annihilate Native American communities. **Myth**

 Although such federal programs existed in the past, none were clinical trials and not within the last decade.



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Myths or Facts

13. Each Native participant on a clinical trial is just a number and receives no personal care. *Myth*

👤 Clinical trials are typically designed to provide the best possible care.


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Myths or Facts

14. Native participants on a “treatment trial” receive at least the current standard of care. *Fact*

👤 Sometimes participation on a treatment trial is a feasible way for a Native participant to at least obtain the standard care.


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Myths or Facts

15. All clinical trials require that the Native participant be well informed before agreeing to take part. *Fact*

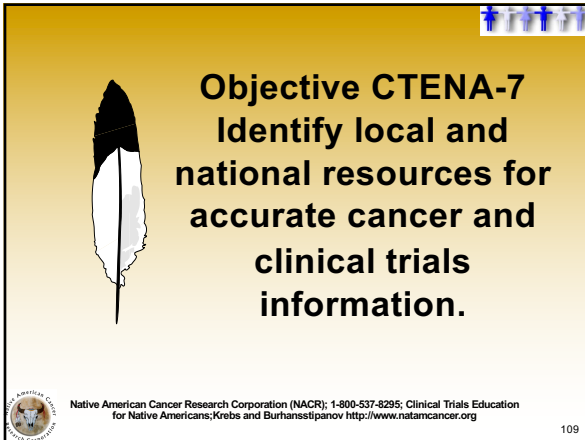
👤 The informed consent process includes the potential participant being able to ask ANY questions about the study desired.

 Native American Cancer Research Corporation (NACR); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org> 108

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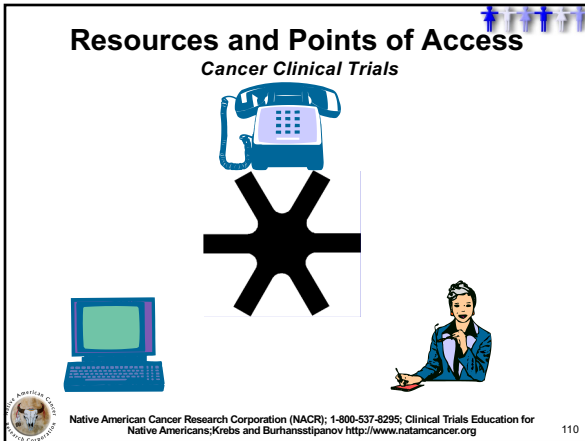
Clinical Trials Education for Native Americans (CTENA)



Objective CTENA-7
Identify local and national resources for accurate cancer and clinical trials information.

Native American Cancer Research Corporation (NACRC); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>

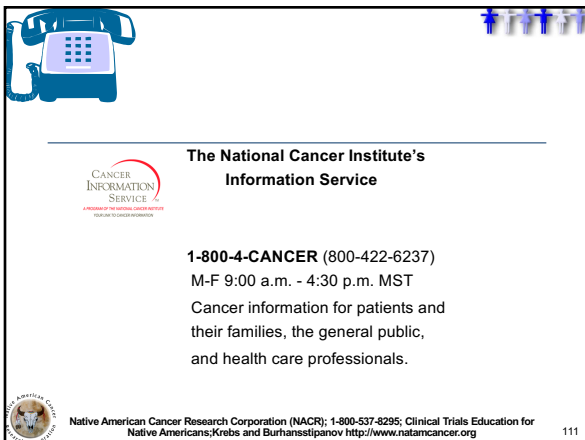
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Resources and Points of Access
Cancer Clinical Trials

Native American Cancer Research Corporation (NACRC); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>

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The National Cancer Institute's Information Service

1-800-4-CANCER (800-422-6237)
M-F 9:00 a.m. - 4:30 p.m. MST
Cancer information for patients and their families, the general public, and health care professionals.

Native American Cancer Research Corporation (NACRC); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>

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Clinical Trials Education for Native Americans (CTENA)

Native C.I.R.C.L.E.
The American Indian/Alaska Native Cancer Information Resource Center and Learning Exchange

Who We Are

The Native C.I.R.C.L.E. is a resource center providing cancer-related materials to healthcare professionals and lay people involved in the education, care and treatment of American Indians and Alaska Natives.

Native C.I.R.C.L.E. Toll-free: 877-372-1617
 200 First Street S.W. Fax: 507-538-0504
 Rochester, MN 55905 E-mail: nativecircle@mayo.edu

Web Page: <http://www.mayo.edu/nativecircle>

Native American Cancer Research Corporation (NACR); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>

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Native American Cancer Research (NACR)
 3022 South Nova Road
 Pine, Colorado 80470-7830

Phone: (800) 537-8295
 Fax: (303) 838-7629
 email: natamilsac@aol.com

Web
Page: <http://www.NatAmCancer.org>

Native American Cancer Research Corporation (NACR); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>

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The Pediatric Oncology Branch
301-496-4256 (you may call collect)

Pediatric branch of the NIH Clinical Center conducts clinical trials for children with cancer. Parents and physicians can also call for consultation and review of current treatment plans.

The Children's Inn 301-496-5672

A very special home-away-from-home for pediatric patients and their families while a child is participating in research at the Clinical Center of NIH.


Clinical Trials Education Native Americans – Obj 06 Myths; NACR Dr. Burhansstipanov: 303-838-9359; Mayo's "Spirit of EAGLES" Dr. Kaur: 877-372-1617; UCHSC "7 Cs" Dr. Krebs: 720-848-0658
 Native American Cancer Research Corporation (NACR); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>

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Web Pages: Resources



Native American Cancer Research Corporation (NACRC); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>

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How to find a computer

- 📁 Tribal Headquarters or Health Centers usually have a computer for public use
- 📁 Someone at the Tribal center may be available to provide instruction
- 📁 Public libraries have people who will help you connect to the Internet

Native American Cancer Research Corporation (NACRC); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org>

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Objective CTENA-8
Examine the potential benefits and drawbacks of participation in cancer treatment clinical trials.



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Clinical Trials Education for Native Americans (CTENA)

Native issues with “inclusiveness”

🗨️ “Why do ‘they’ always want to experiment on us?”

 Native American Cancer Research Corporation (NACR); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org> 118


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Anecdotal Data

🗨️ John (Northern Plains Tribe) was asked why he was taking part in a clinical trials study. “Our tribe has always believed that we need to help the next generation...

🗨️ My participation is a gift so that those who come after me suffer less ...


🗨️ and are cured of this disease.

 Native American Cancer Research Corporation (NACR); 1-800-537-8295; Clinical Trials Education for Native Americans; Krebs and Burhansstipanov <http://www.natamcancer.org> 119

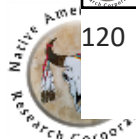
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Potential Benefits


🗨️ QUESTION: What do you think are potential “benefits” of clinical trials participation for Native cancer patients or their family members?

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The Study Protocol

QUESTION:

- 🗨️ What does “study protocol” mean?
- 🗨️ Study protocol explains the steps and processes involved in a study

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The Study Protocol

QUESTION: What does “study protocol” mean?

- 🗨️ who is involved? What is to be done?
- 🗨️ by whom? When is it to be done?
- 🗨️ where will it occur? Why is it being done?
- 🗨️ step-by-step explanation of “how” it is to be done


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Benefits / Drawbacks


| Potential Benefits | Potential Drawbacks |
|--------------------------------|---|
| 🗨️ Access to high quality care | 🗨️ Study protocols may be difficult to follow |
| 🗨️ latest, most advanced care | 🗨️ may interfere with normal daily function |

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Benefits / Drawbacks




| | |
|---|--|
| Potential Benefits  participant receives “at least” the current standard treatment available | Potential Drawbacks  QUERY: Are our patients currently receiving standard cancer care? No |
|---|--|


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Benefits / Drawbacks










| | |
|--|--|
| Potential Benefits  Better understanding of how the treatment may work in other Native participants | Potential Drawbacks  Treatment may not work as well in Natives as in other populations  Responsiveness to medication? |
|--|--|


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Benefits / Drawbacks


| | |
|---|--|
| Potential Benefits  Access to:  on-going medical care  monitoring  routine follow-up | Potential Drawbacks  Barriers  Transportation  Child care  Time off from work  Time “constraints” |
|---|--|

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Clinical Trials Education for Native Americans (CTENA)




Benefits / Drawbacks

| | |
|--|--|
| <p>Potential Benefits</p> <p>👤 All participants supposed to be treated the same</p> | <p>Potential Drawbacks</p> <p>👤 Individual's cultural, spiritual needs may not be addressed / respected</p> |
|--|--|


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Benefits / Drawbacks

| | |
|--|---|
| <p>Potential Benefits</p> <p>👤 Native participant needed to smudge each time before receive treatment ...</p> | <p>Potential Drawbacks</p> <p>👤 delayed hospital scheduling for the treatment room</p> |
|--|---|


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Benefits / Drawbacks


| | |
|---|---|
| <p>Potential Benefits</p> <p>👤 participant can withdraw from a study at any time (e.g., severe side effects)</p> | <p>Potential Drawbacks</p> <p>👤 participant's severe side effects may be temporary ... but once withdraw, unlikely to be allowed to re-enroll in the trial</p> |
|---|---|

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Benefits / Drawbacks

| | |
|--|---|
| <p>Potential Benefits</p> <p>🗨️ If the new treatment works, the participant is among the first to benefit</p> | <p>Potential Drawbacks</p> <p>🗨️ New treatments under study are not always as good or better than the standard treatment</p> |
|--|---|


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Benefits / Drawbacks

| | |
|--|---|
| <p>Potential Benefits</p> <p>🗨️ participant can contribute to improved cancer care for others</p> | <p>Potential Drawbacks</p> <p>🗨️ The participant may not personally benefit from the treatment</p> |
|--|---|


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Interactive exercise...please work in pairs

- 🗨️ A tribal leader was recently diagnosed with an advanced stage of prostate cancer.
- 🗨️ QUESTION: Is prostate cancer a problem for Native men?

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Interactive exercise...please work in pairs


- Yes, it is among the more common types of cancer that Native men develop
- Native men have the poorest survival from prostate cancer in comparison with other racial groups

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Interactive exercise...please work in pairs


- The tribal leader's provider told him that he was eligible for a treatment trial... but that there may be severe side effects ...such as ... he:
- may not be able to have an erection
- may need to wear a diaper
- may have a lot of pain

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Interactive exercise...please work in pairs

- Since the side effects are so severe, what potential benefits might there be for him to participate?
- In your opinion, do the potential benefits out-weigh the potential side effects?

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Interactive exercise...please work in pairs

- Every clinical trial has some benefits and some drawbacks. The Native participant needs access to all of the information to understand both the potential benefits and drawbacks
- Then the participant and the family can make an informed decision about participation

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Objective CTENA-9
Describe the impact of Native cultural perspectives on health and experience of cancer and clinical trials.

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Cultural perspectives of health and cancer

- Native "world views" differ from Non-Native cultures including the causes, expression and treatment of "cancer"

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Cultural perspectives and impact on participation in clinical trials


- 🗣️ Perceptions of the provider?
- 🗣️ Perceptions of the potential participant?

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Example


- 🗣️ Unique issues facing American Indians and Alaska Natives in getting breast cancer care

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Culturally specific issues


- 🗣️ “Cancer” not discussed within most Native cultures
- 🗣️ “Prevention” and “early detection” are unusual concepts within the cultures
- 🗣️ Breast cancer has “cultural” interpretations that vary among Tribal Nations

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Culturally specific issues

- 📖 For many the perceived “cause” of the cancer impacts timely participation in treatment.
- 📖 **QUESTION :**What are examples of how colon cancer may be perceived by a Native American patient?



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Culturally specific issues

- 📖 Travel to treatment = childcare issues
- 📖 Long absence = job stability issues
- 📖 Partner gone for subsistence hunting/fishing
- 📖 Low priority ranking from CHS
- 📖 CHS out of money until next fiscal year



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Culturally specific issues

- 📖 Too few people diagnosed with cancer within local community to justify the high cost for an oncology specialist
- 📖 Too few people trained in the field of oncology
- 📖 **QUESTION:** What are some reasons why there are no oncologists?


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Culturally specific issues


- 📌 Lack of access to state-of-the-art care (e.g., lumpectomy)
- 📌 2% had access to lumpectomy ... Partially because it typically requires 6 weeks of radiation ... Where do you live during the radiation treatment?
- 📌 “Services” (CHS) by Tribal health programs for cancer referrals

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Culturally specific issues


- 📌 a. Lack of access to second opinion
- 📌 b. “Delays” in processing CHS paperwork for referrals to diagnostic mammogram/biopsy

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Culturally specific issues


- 📌 c. “Priority List” allows for top 1-3 to be sent for referral; abnormal mammogram typically is “prioritized” as “7” or “8”
- 📌 d. Dx early in Federal fiscal year = “quicker” referral as compared to referral in July, August, September

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Culturally specific issues

- e. Quality of care provided by CHS oncologist typically located elsewhere
- Reminder: IHS CHS funding is set by Congress and the percentage of support for each tribe's documented health care varies from 23% to 60%




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Culturally specific issues

- "White man's" disease
- Punishment (from your actions or a family member's actions)
- "Wear the pain" to protect other members of one's communities




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Culturally specific issues

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Clinical Trials Education for Native Americans (CTENA)




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Clinical Trials Education for Native Americans (CTENA)



Cultural Perspectives and Cancer Diagnosis


- 👤 “White man’s” disease
- 👤 Punishment (from your actions or a family member’s actions)
- 👤 “Wear the pain” to protect other members of one’s communities



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Cultural Perspectives and Cancer Diagnosis


- 👤 Natural part of one’s path and the lessons to learn
- 👤 Doctor’s shoot a hole through your spirit when they diagnose you with cancer (results in depression, fear rather than trust ...etc.)



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Cultural Perspectives and Cancer Diagnoses

- 👤 Results from a curse from someone or violation of tribal mores (stepping on a frog, urinating on a spider)
- 👤 Contagious (virus or “spirit”)
- 👤 Environmental racism
- 👤 Stress / negative feelings




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Cultural Perspectives and Cancer Diagnosis

- 🍽️ Certain foods
- 🗣️ Spread by saying the word, "cancer"
- 🍀 Bad luck
- 🧐 May be a realistic fatalism ...
- 🏥 e.g., no access to quality treatment
- 🎲 Fatalism / pre-destination




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Cultural Perspectives and Cancer Treatment

- 🏠 The patient's own health may be a low priority (especially women) -- treatment decisions often delayed
- 👨‍👩‍👧‍👦 Whole family involved with the treatment and recovery (decision-making)




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Cultural Perspectives and Cancer Treatment

- 👨‍👩‍👧‍👦 Rely on key family member to make important decisions
- 👨‍👩‍👧‍👦 Spouse makes all decisions
- 👨‍👩‍👧‍👦 Elder family member may make decisions
- 👨‍👩‍👧‍👦 Other family members
- 👨‍👩‍👧‍👦 Family may choose to not inform patient of diagnosis or treatment options




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Cultural Perspectives and Cancer Treatment

- 📖 Conflict between contemporary medicine with Traditional Indian Medicine (TIM)
- 📖 Ceremonies, teas, prayer
- 📖 5. Confusion between "treatment medication" and "pain medication"




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Cultural Perspectives and Cancer Treatment

- 📖 The need to take on the disease to protect family members (unlikely to use contemporary medicine) (similar to "wearing the pain")
- 📖 The use of herbal treatments / supplements (complementary versus alternative)



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Cultural Perspectives and Cancer Treatment

- 📖 May believe in fate
- 📖 May believe whites receive "real" treatments and others are victims of experimentation
- 📖 May refuse treatment to spiritually atone for some past misdeed




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Cultural Perspectives and Cancer Treatment

- 👤 May wish to go home (to feel safe and/or to maintain sense of control)
- 👤 May mean inadequate or no treatment
- 👤 May delay initiation of treatment
- 👤 May wish to go through ceremony (atonement, preparation for death)




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Cultural Perspectives and Cancer Treatment

- 👤 May wish to return to traditional cultural lifestyle
- 👤 May have different cultural perceptions of time (may not follow timing of treatment regimen)




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Cultural Perspectives and Cancer Treatment

- 👤 Treatment may require loss of body part (e.g. limb amputation, mastectomy) and may affect spiritual path
- 👤 "If I have my breast removed, my body / spirit is changed and my ancestors on the other side of the river will not know how to find me when I move on. I will be alone for eternity."



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Cultural Perspectives and Research Participation

- Many people perceive being in research makes one a “guinea pig”
- Belief that cancer cannot be cured
- ... why bother going through a study?



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Cultural Perspectives and Research Participation

- Distrust of researchers
- Believe benefits are limited only to the researcher
- Promotion
- Publication
- Patients
- Wealth



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Cultural Perspectives and Research Participation

- Traditional cultural healing excluded
- No community benefit (limited to no improved access to services)
- Distrust of how research institutions will use the study findings
- annihilation



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Cultural Perspectives and Research Participation

- ☞ Sense of “ownership” of the research is less common among disenfranchised communities
- ☞ lack of ownership results in lower participation.
- ☞ feel separate, believe benefits only for mainstream community




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Cultural Perspective and Clinical Trials

- ☞ Cancer, much less clinical trials, often are of low priority compared to other health/life issues.
- ☞ Participating in research, like clinical trials, may be taboo
- ☞ Research results rarely shared with community




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Cultural Perspectives and Clinical Trials

- ☞ Spiritual aspects of cancer are not acknowledged by clinical trials
- ☞ Hesitancy of some providers to collaborate with traditional healer
- ☞ Community not involved in designing research protocols




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Cultural Perspectives and Clinical Trials

- Providers may not refer under-represented populations to clinical trials
- Perception that the under-represented are less likely to comply with trial protocols



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Cultural Perspectives and Clinical Trials

- May need Tribal IRB Approval
- May need / want to participate in ceremony prior to enter clinical research
- May need more financial assistance than may be available for the protocol




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Interactive Activity



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Interactive Activity

Work in pairs please


- The SELECT Trial is a prostate cancer prevention study that uses a special diet.
- Men consume vitamins and nutrients that may be helpful in the prevention of prostate cancer
- selenium and vitamin E

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Interactive Activity


- The trial will provide regular prostate screening
- which is difficult for many Natives to obtain from their home settings
- Your tribe has to identify prostate cancer as an important health priority

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Interactive Activity

- Prostate cancer screening can be invasive digital rectal exam
- or prostate cancer screening can be relatively easy blood test: Prostate-specific-antigen (PSA)

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Interactive Activity

🗣️ In your opinions, what types of cultural or health issues related to this disease and this trial do you feel will influence local Native men's decision about whether or not to participate?

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Objective CTENA-10
Examine selected cultural, ethical, social, spiritual and political issues related to Native American's participation in clinical trials.

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🗣️ **QUESTION:** What is culture?

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Definitions of culture

(NOTE: definitions of culture vary widely, these are some examples.)

Example 1. Culture is a patterned way in which humans have learned to think about, and act in, their world. (Bates in Boyle)

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QUESTION

OPINION ONLY

Do you think the culture of the provider / recruiter influences the communication with the patient regarding clinical trials participation?

a. yes
b. no

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Interactive: Your Culture

What is your culture?

What are aspects of your own culture that are of particular importance to you?

How might these aspects impact your recruitment of participants to a clinical trial?

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Ethical Issues and Clinical Trials Participation

👤 Altruism (for the community)

🗨️ “I am dying of cancer and I chose to take part in this trial because, according to my tribe, I am supposed to leave something behind for my children. This is my gift to them.”

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Ethical Issues and Clinical Trials Participation

👤 Who will benefit?

- 🗨️ Improved access to care
- 🗨️ Improved quality of care
- 🗨️ Only available treatment
- 🗨️ Improved chances of survival


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Ethical Issues and Clinical Trials Participation

👤 “Prevention” or “early detection” trial


- 🗨️ what if there are insufficient treatment monies available from the tribal health program for those diagnosed with cancer during the trial?

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Ethical Issues and Clinical Trials Participation

- Clinical trials for hereditary form of cancer
- how are family members informed?




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Ethical Issues and Clinical Trials Participation

- "Justice" to have Native people with diabetes and other conditions (excludes them from the eligibility)
- Wealthy and well-educated have "access" to clinical trials' opportunities ... (distributive justice)




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Ethical Issues and Clinical Trials Participation

- "Autonomy" for people living off reservation and no access to care
- A few Tribal Nations mandate that no tribal member, regardless of where they live, may participate in clinical trials or any other type of research unless Tribal IRB has approved the study protocol



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Ethical Issues and Clinical trials Participation

- 📖 “Autonomy” Tribal social structure that mandates elder to make health decisions for all family members
- 📖 Protocols that rely on telephone access



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Ethical Issues and Clinical Trials Participation

- 📖 TIM and behaviors that interfere with adherence to CT protocols
 - ⊕ *the need for prayers and ceremonial burning of sage / cedar prior to chemo?*
 - ⊕ *impact on others in the treatment room?*



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Spiritual Issues and Clinical Trials Participation

- 📖 Complementary and Alternative Medicine
- 📖 Inclusion of prayer / spirituality on studies examining quality of life
- 📖 Synergistic effects of TIM herbal tea preparations and medication absorption / metabolism



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Clinical Trials Education for Native Americans (CTENA)

Political/Legal Issues and Clinical Trials Participation

- Tribal Health Board and approval of the trial?
- Who pays for the medication?
- Who pays for the treatment?
- Who educates the family related to protocol-specific care when home?

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Political/Legal Issues and Clinical Trials Participation


- Tribal IRB approval needed before recruit tribal members for participation
- Tribal leaders want an active role in designing the research protocols

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Political/Legal Issues and Clinical Trials Participation

- Native people worried that the private information collected in the study will be shared with others without their consent
- Payment incentive is offered for participants that is not “coercive” to others, but IS to Natives (\$30)

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Political/Legal Issues and Clinical Trials Participation

- 🗳 Informed consent process uses technical language that is not understandable to the potential Native participant
- 🗳 Informed consent process is rushed through



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Social Issues and Clinical Trials Participation

- 🗳 Tribal ostracism for
 - ⌚ (1) cancer diagnosis
 - ⌚ (2) participation in research
- 🗳 Family / community support for the patient and for the care-giver




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🗳 Interactive Activity





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 **Background:**

-  Study of Tamoxifen and Raloxifene (S.T.A.R.) Trial
-  for the prevention of breast cancer








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Interactive Activity


 **Examples of STAR Eligibility Criteria**

-  35 years old or older
-  Post menopausal (no more moons)
-  No hormone therapy for at least 3 months
-  No problems with blood clots







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Interactive Activity

-  Breast cancer varies among ethnicities
-  Native Hawaiian women have among the highest breast cancer mortality rates
-  Native Hawaiian and Native American women are frequently diagnosed at advanced stages of the disease




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Interactive Activity


-  Breast cancer varies among ethnicities
-  American Indian women have the poorest survival from breast cancer
-  Breast cancer has a higher incidence among northern Plains tribes than among those living in the southwest




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Total Number of Deaths and Age-Adjusted Cancer Mortality Rate for Breast, By Region, 1994-98




| | | | | | |
|-----------------|-----|-------|-------|-----|--------|
| U.S. All Races | 385 | 11.1 | 0.3 | 383 | 24.0 |
| All IHS Regions | | | 2 0.1 | | 14.2** |
| Alaska | 33 | 11.1 | | 33 | 20.8 |
| East | 109 | 7.5** | 0 0.0 | 108 | 13.4** |
| No. Plains | 75 | 12.0 | 1 0.2 | 75 | 21.6 |
| Pacific Coast | 92 | 8.8** | 0 0.0 | 92 | 16.2** |
| Southwest | 76 | 5.2** | 1 0.2 | 75 | 9.2** |





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Interactive Activity

-  Breast cancer varies among ethnicities
-  Lesbian women tend to be under-diagnosed and treated and consequently experience elevated death rates




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🗨️ Working in pairs, please discuss...

🕒 What cultural issues do you feel might influence American Indian women's decisions about whether or not to participate in a trial like S.T.A.R?




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Objective CTENA-11
Describe the benefits and drawbacks of using traditional Indian medicine in cancer care and clinical trials.



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Traditional Indian Medicine(TIM), Complementary and Alternative Medicine

🗨️ QUESTION: How common is the use of TIM in Indian Country?


🕒 Estimates are between 25%-70% of the Native population



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Traditional Indian Medicine (TIM), Complementary and Alternative Medicine


- 📊 34% use among cancer patients of all races
- 🌐 Among Native cancer patients, the estimates of use are closer to 50%



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TIM Research Questions raised by Natives

- 📊 Does participation in traditional Indian ceremonies influence the immune system?
- 📊 How do traditional Indian teas and their preparation influence drug absorption (e.g. chemo)?



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TIM Research Questions raised by Natives

- 📊 Do spiritual healing ceremonies influence recovery from invasive cancer treatments?
- 📊 Is the cancer patient's support affected by family involvement in traditional ceremonies?




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TIM Research Questions raised by Natives


- How does spirituality affect a Native cancer patient's health?
- How do traditional Indian practices contribute to the prevention of disease?
- How does TIM reduce the side effects of cancer treatment?



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TIM Research Questions raised by Natives


- The Office of Alternative Medicine recognizes that some traditional healing techniques provide health benefits
 - Herbal tea preparation for relief of pain in a Native with stomach cancer



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Benefits of Clinical Trials including TIM

- Clinical Trials of TIM may address "supportive care" benefits obtained through ceremony
- Study treatment approach is less toxic /invasive



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Benefits of Clinical Trials including TIM

- Successful TIM clinical trials can increase the scientific recognition of TIM effectiveness
- ... and increase acceptance of these therapies to help others



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Drawbacks of using TIM while on a Clinical Trial

- TIM "treatments" may interfere with clinical trials
- TIM may affect medication absorption
- ... important for M.D. to know what is being taken as part of the traditional healing therapy



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Drawbacks of using TIM while on a Clinical Trial

- TIM may affect decisions about taking part in clinical trials
- TIM may affect eligibility
- TIM may affect adherence to study protocols



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Interactive Activity

🗣️ Form groups of 3 please

- 👤 Your group represents Tribal family members -- specifically siblings
- 👤 Your brother is a 5-year survivor of colon cancer.


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Interactive Activity

🗣️ He has had some long-term side effects from the cancer experience, of which fatigue is a major barrier to his quality of life.


🗣️ The NCI has announced a trial that is designed to determine if participation in Pow Wow dancing to reduce fatigue (i.e., increase energy level)

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Interactive Activity

🗣️ Your brother has asked for your opinion regarding his potential participation in this study.

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Interactive Activity


In relation to traditional tribal beliefs:

- What are the potential benefits to your brother participating in such a spiritual clinical trial? List at least 2
- What are the potential drawbacks to your brother participating in such a spiritual clinical trial? List at least 2

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Objective CTENA-12
Identify the Tribal research approval process relevant to clinical trials.


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“Institutional Review Board” (IRB)

QUESTION: What is an “IRB”?

- The IRB reviews research and consent forms to determine if rights and welfare of subjects are protected.
 - Multiple legal and ethical roles and responsibilities

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What does the “IRB” do?


- 📋 Works for the benefit and respect of the community
- 📋 Makes certain that all research follows 3 principles of ethics:
 - ⊕ respect for persons
 - ⊕ benefits outweigh harm
 - ⊕ justice

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What does the “IRB” do?


- 📋 IRB Shares responsibility with the research investigator for protecting the:
 - ⊕ privacy
 - ⊕ safety
 - ⊕ confidentiality of the people who participate in the study

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What does the “IRB” do?

- 📋 IRB conducts “initial” and “continued” review (6 mos. to a year renewals)
- 📋 The IRB assures that the study is scientifically sound

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What does the “IRB” do?


- Will the study findings be important?
- Is the study sample large enough to draw conclusions? (i.e., statistical methods)

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What does the “IRB” do?


- Sometimes researchers are so excited about a discovery, they may forget that people are unique cultural beings
 - People become objects, symbols on paper, figures in a formula, impersonal ‘subjects’ in a scientific study

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What does the “IRB” do?

- Assures the investigators are qualified to conduct the study as specified in the research design
- Documents provided by investigator(s) to the IRB contain enough information to allow valid judgments about the science and ethics of the research

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What does the “IRB” do?


- 📋 Conduct “continuing” review (at least once each year)
- 📋 IRB has the authority to approve, modify or disapprove research activities.

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The “IRB” determines


- 📋 Risks to the subjects
- 📋 Anticipated benefits to the subjects and others
- 📋 Importance of the knowledge that may reasonably result from the study
- 📋 Informed consent process to be employed

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Who serves on the “IRB”?

- 📋 At least 5 members with diverse backgrounds
- 📋 Both males and females
- 📋 Non-scientific member
- 📋 Scientific members

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Who serves on the “IRB”?


- Non-affiliated” members
- Potential participants of study
- Consumers(members of the community who do not have advanced degrees — ‘regular’ community members)

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Who serves on the “IRB”?


- Scientists
- Researchers
- Religious leaders
- Community leaders
- Adolescents

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How does a “Tribal IRB” Differ from an “Academic IRB”?

- Tribal IRB must adhere to all of the federal legal requirements and responsibilities as does any other IRB
- Tribal IRBs primarily include Native members

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How does a “Tribal IRB” Differ from an “Academic IRB?”


- Tribal IRBs can have additional “research guidelines” to which all studies must adhere (i.e., additional “level” of protection for the tribe)
- ... all IHS research must be approved by tribal governments and the tribes’ consent must be “informed.”

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Can any Tribal Nation create its own IRB?


- Yes, after participating in IRB training and the Tribal Council is willing to assume the legal and ethical responsibility.
- But it is still very challenging. Many mandates from NIH

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When does the Regional / Area IHS IRB and National IHS IRB become involved in the review, approval, denial of a research application?


- Any time IHS personnel, facility, equipment, and funds are incorporated within the implementation of the study design.

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Does the Tribal Nation also have to use the IHS IRB in addition to the Tribal IRB?

- If any IHS personnel, facility, equipment or funds are involved in the study, then the IHS IRB approval needs to be obtained.




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Can a Tribal Nation use the IHS IRB?

- The IHS has offered use of its “Area” and “National” IRB to Tribal Nations who would like to access its services, guidance, and protection.
- Also, if IHS facility, equipment or funds are involved in the study, then the IHS IRB approval needs to be obtained.




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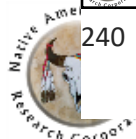
What if the proposed study does not use any IHS facilities, etc.?

- The Tribal / urban health board can request the IHS IRB to review the application.
- The Tribal / urban health board can submit the application to a collaborating academic organization.



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What if the proposed study does not use any IHS facilities, etc.?


- The Tribal / urban health board can seek "Single Project Approval" from the federal agency who is funding the application.

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What Are Examples of "Human Subject" Issues?


- Participant inclusion criteria
- Participant exclusion criteria
- Participation of "vulnerable" people
- Inclusion of women, including childbearing, and men

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What Are Examples of "Human Subject" Issues?

- Inclusion of children
- Inclusion of racial and ethnic diverse participants
- Potential "risks" of the study
- Potential "benefits" of the study

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What Are Examples of “Human Subject” Issues?


- Alternatives for the participants other than participate in the study
- Recruitment efforts (“equal” and feasible within specified time frame)
- Justification of any incentives people may receive

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Are Examples of “What Human Subject” Issues?


- Justification of any costs that people may incur
- Informed consent process clarified

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Informed Consent Process Clarified


- Who administers, when, where, how
- What information shared
- Understandable by potential participant
- Voluntary participation and withdrawal

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Informed Consent Process

- Statement that the study involves "research"
- Purpose of the study
- Clarify how long participant involved in the study
- Describe the procedures
- Identify any procedures that are experimental

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Informed Consent Process

- Description of risks or discomfort to participant
- Description of benefits to participant or others
- Explanation of alternatives available other than participate in study

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Informed Consent Process

- Description of confidentiality protections to be used
- If more than minimal risk, description of medical treatment and compensation

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Informed Consent Process


- 🗨️ Clarification of who to contact with questions /concerns
- 🗨️ Reassurance that participation is voluntary at any time; participant can withdraw with no risk of penalties



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Insufficient “Informed Consent”

- 🗨️ Making a choice versus being a guinea pig
- ⊕ Involuntary sterilization of Indian women (1960’s)
- ⊕ Hepatitis B vaccine in Alaska Native children (1990’s)



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Examples of Cultural Concerns & Clinical Trials

- 🗨️ Fear of annihilation, genocide
- 🗨️ Storage of specimens
- 🗨️ Fear of not receiving “best” care (i.e., “sugar pill”)
- 🗨️ Preliminary research conducted on sacred animal (i.e., “relation”)



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