rETHICS

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Contents

Section 1. Research with AIAN Communities

This training is written for American Indian and Alaska Native (AIAN) community members conducting research with AIAN communities. Federally funded grants require people who are conducting research to be trained in research with people. The purpose of this training is to culturally adapt a research training that prepares researchers to conduct ethical research with AIAN communities.

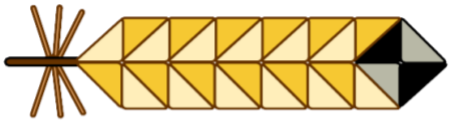
There are 10 sections in this training. Each section is about 3-8 pages and includes boxes to the right and left of the text which highlight important information and give examples of the content being discussed. Links to additional information are also provided throughout the text. There are short quizzes for sections 2-10. Each quiz consists of 3-5 questions. You can stop the training at the end of each quiz and return again at a later time to finish.

Learning Objectives

- Be aware of the history of research in Indian Country
- Understand tribal sovereignty in research

Conducting Ethical Research

Many Native people have an individual as well as a group or tribal identity. They often have a sense of responsibility to their family as well as to their communities. When conducting ethical research in AIAN communities, it is important to consider how researchers and community members can respectfully learn from each other. What does it mean to approach research in a good way? What are the ethical values that Native people hold which guide the research that they do?



Many terms are used to describe Indigenous people in the U.S.

For the purposes of this training, ***AIANs*** and ***Native people*** refer to American Indian and Alaska Native people.

The terms ***AIAN communities*** and ***tribal communities*** refer to reservations, pueblos, rancherias, villages, AIAN and tribal organizations, and urban groups of AIAN people.

A ***tribe*** refers to an AIAN society linked by various aspects of culture.

Many traditional stories teach us how to conduct ourselves in a good way. For example, trickster stories offer teachings about how not to act. A trickster, such as Coyote or Raven, often behaves in ways that are inappropriate or harmful to individuals or the community at large. Learning about the values embedded in these stories from communities and understanding how to apply them in research are important aspects of conducting ethical research within AIAN people.

Roots of Scientific knowledge in AIAN Communities

Native people have always been researchers. AIAN ancestors observed, asked questions, experimented, tested, and engineered new solutions that resolved issues in everyday life. They then shared these solutions to benefit the entire community.

Over time, AIAN communities have accumulated vast amounts of knowledge about the natural world. They have used their understanding of stars and seasons to navigate and mark important planting and harvesting events. They also used this knowledge to treat illnesses such as the common cold, depression, and cancer. Today, Native people continue to use their observations and knowledge to improve life in their communities. These three examples show how AIAN knowledge continues to impact agricultural, medical, and scientific fields today.

Many tribes have grown corn that is strong, disease-resistant, and that thrives under specific environmental conditions. Corn was also grown alongside beans and squash because they benefit from growing together.

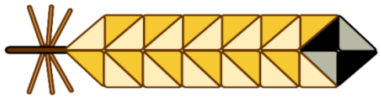
AIANs have used bitterroot for cold care. Chewing the roots releases menthol, which soothes sore throats and coughs.

Many tribes have used willow bark to treat fevers and pain. Willow bark contains salicylic acid, which Western scientists eventually used to develop aspirin.

Tribal Sovereignty and Research

Tribal Sovereignty. Tribes have the inherent right to make their own laws, enact regulations, and determine what research can take place on their lands. Tribal sovereignty has important implications for research. Tribes may:

- Approve or deny requests for research.
- Decide how research is reviewed and conducted.
- Require research activities to stop.
- Review research reports, press releases, or publications before they are publicly shared.
- Negotiate exclusive or shared ownership of research results.
- Decide if, how, and what cultural knowledge or practices are shared.
- Restrict use of tribal names and identification in research reports.



Federally-recognized tribes have inherent sovereignty recognized by U.S. law. Some tribes have state recognized sovereignty. Other AIAN communities or organizations may have special relationships at a state or local level that establishes a legal status unique to their position in the community.

Summary

Guided by traditional AIAN values to conduct research in a good way, the purpose of this training is to culturally adapt a research training that prepares researchers to conduct ethical research with AIAN communities. More importantly, it will act as a guide for research conducted with AIAN communities.

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Section 2. The History of Ethical Regulations

Learning Objectives:

- Understand the history of ethical regulations and why they are needed
- Define the three Belmont principles of Respect for Persons, Beneficence, and Justice
- Identify how these principles apply in Native communities

Introduction

While conducting research with AIAN communities, researchers have an ethical obligation to:

- Respect the rights of an individual's choice to participate in research (Respect for Persons).
- Make sure the selection of persons to participate in research is fair (Justice).
- Do good, maximize the benefits, and minimize harms from research (Beneficence).
- Establish trust with individuals and communities who participate in research.
- Conduct research that benefits Native people.

In this section, we first provide a brief overview of the history of ethical regulations of research. We also discuss why and when these laws were created. We follow with the three primary principles of ethical research and discuss how these apply to working with AIAN communities.

History of Ethical Regulations

Research in the U.S. and throughout the world has a troubled and at times unethical history. Some published research findings have contributed to ***stigmatizing*** tribes and Native people, resulting in harm to individuals and communities, and creating a fear of research and distrust of researchers among some AIAN people.

Stigma is a set of negative and often unfair beliefs that members of a society have about a group of people.

Other groups have also experienced mistreatment from research. The first documents to regulate research apply internationally and were created following the Holocaust. Nazi doctors and scientists conducted human rights abuses on concentration camp prisoners and attempted to justify these abuses as falling under medical research.

Despite these regulations, from 1973 through 1976, doctors at the Indian Health Service sterilized 3,500 Native women. The consent forms were inadequate, illegally obtained, and not in compliance with regulations.

The study that established the U.S. National Research Act in 1974 and that led to the creation of the Belmont Report and the Common Rule was the ***Public Health Service Tuskegee Study***. Researchers in the U.S. withheld syphilis treatment for 600 African American males for forty years to learn about the life cycle of syphilis, leading to the eventual death of many participants. In response to these abuses and many others, the U.S. increased the protections of human participants in research.

Brief History of Ethical Principles

1947 The Nuremberg Code was developed in response to Nazi abuses and states that "voluntary consent of the participant is absolutely essential."

1964 The Declaration of Helsinki was developed by the World Medical Association and defines ethical principles of research.

- Research with people should only occur after findings from basic science and animal experiments.
- Research protocols should be reviewed by an independent committee.
- Informed consent from research participants is necessary.
- Research should be conducted by qualified individuals.
- Risks should not exceed the benefits of research.

1979 The Belmont Report created ethical principles that are the foundation for research in the United States. Federal policy about how to uphold these principles are referred to as ***The Common Rule Subpart A of 45 CFR 46***.

The Three Ethical Principles of Research in the *Belmont Report*

The ***Belmont Report*** describes how to conduct ethical research with people. It includes three ethical principles: ***Respect for Persons, Beneficence,*** and ***Justice*****.** While these principles were written to protect an individual involved in research, they also apply to whole communities in AIAN research settings.

Respect for Persons

Respect for Persons is about respecting the rights of individuals to choose to participate in research. In the 1960s, a student at Washington University in St. Louis started the ***Tearoom Trade Study***. He told men he would serve as a lookout for police as the men engaged in homosexual acts in public restrooms. He first studied men with college degrees without telling them. Later he told them that he was a researcher and conducted interviews. To include men with less education, he secretly followed them and wrote down their license plates. Later, disguised as a health interviewer, he went to their homes and asked questions about their race, education, marital status, and other private information. The tearoom trade study violated the ethical principle of ***Respect for Persons*** because he failed to give the men information about his study and failed to give them a choice to participate. He also failed to protect the men's rights to privacy. Respect for persons asserts individuals have the right to ***autonomy*** and includes two rules:

Autonomy is the ability of a rational person to make an informed decision without undue influence or coercion.

1. People have the right to decide for themselves if research is right for them and if they want to participate.

1. They must be allowed to make decisions about what they do and about their own wellbeing.
2. They must be given the choice to be in a study and be given enough information to make that choice.
3. Participants have the right to privacy and confidentiality.

2. People who cannot make decisions by themselves have the right to be protected.

- People who cannot make decisions by themselves may not understand the study or how being in the study might affect them. Researchers must add steps to make sure these people have their rights protected.

Respect for Community

It is also important to respect the rights of communities during the research process. In other words, respect for persons should be applied beyond the individual to communities as well. Respecting AIAN tribal sovereignty and community autonomy is critical to building trust. Gaining trust requires active listening, a humble approach, and acknowledging the expertise that each member of the community brings to the research. Respect for community shows that you are invested in the relationship and that you are working to create an equitable partnership in research.

Researchers must make sure that:

- AIAN communities have the time, space, and privacy to make decisions about the research that is conducted within their communities.
- AIAN communities are offered the choice to be in a study and should be given enough information to make that choice.
- In tribal settings, tribal approval is obtained.
- In urban settings, meaningful discussions with urban AIAN leadership take place and AIAN groups provide permission for the research.
- AIAN communities' privacy is protected and confidentiality is maintained.

Havasupai Lawsuit against ASU

In 1989, Arizona State University (ASU) researchers studied diabetes with the Havasupai Tribe. They collected blood samples and tested to see if people with certain genes were more likely to develop diabetes.

The researchers did not find a gene for Type 2 Diabetes. The researcher in charge permitted researchers and graduate students to use the blood samples for studies on mental illness and other topics. Using the blood samples, they published papers that named the tribe. The papers described tribal migration, going against the Havasupai creation story. The participants as well as the tribal council said that the use of their blood samples did not fit with their agreement when they consented to be a part of the research. They also felt the unapproved use of the papers harmed the Havasupai Tribe by stigmatizing the community.

The tribe sued in 2004. They reached a settlement outside of court in 2010. As a result, the Havasupai Tribe received $700,000 and the blood samples were returned to the tribe.

Beneficence

Beneficence is about doing good, maximizing the benefits, and minimizing the harms resulting from research. In other words, beneficence requires that the ***risks*** of research are justified by the ***benefits*** of research. The principle of ***beneficence*** includes respecting people's decisions, protecting people from harm, and securing their wellbeing throughout the research process.

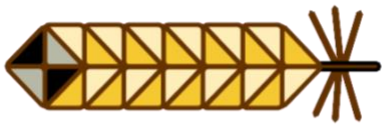
Nothing in life is risk-free. The ethical standard for human subjects research is that risks are minimal and not greater than risks experienced in everyday life, unless there is a considerable benefit or promise of the research that justifies a greater level of risk. Balancing risks and benefits in a study can be difficult and can be biased by a researcher's judgment, culture, and interpretation of AIAN community norms. Working together with communities and individuals involved in a study can help ensure the principle of beneficence is upheld.

Beneficence is a research obligation shown through:

1. Doing no harm (doing good).
2. Maximizing possible benefits and minimizing possible harms.
3. Benefitting Native people.

A value common across AIAN communities is to ***"do good,"*** which is an aspect of the research principle of ***beneficence***. Hundreds of years of genocide, policies outlawing AIAN cultures, and trauma caused by colonization have made it even more important that research benefits Native people. Involving community members throughout the research process helps to make sure the values of ***respect*** *and* ***justice*** are included in the research efforts. This process of community involvement also makes sure the research will likely benefit AIANs. Community members provide knowledge and experience to identify challenges, possible harms, and benefits that the study may bring.

AIAN people have long experienced poorer health outcomes compared to other Americans. Poverty, discrimination, and education have an impact on health. In the face of these challenges, AIAN communities are still here. Native people rely on many cultural and community strengths to help them through these challenges. Culturally adept research seeks to build upon these strengths. Focusing only on the negative can stigmatize AIANs as a group, resulting in harm. Good research requires a purposeful approach to improve AIAN health and wellbeing. Research with AIAN communities can result in evidence-based programs that reflect Indigenous values, and expand wellness opportunities. To ensure research is a good fit for the community, ask yourself if the research will benefit AIAN people and their communities or if it is simply for the sake of research.



To learn more about conducting good research in AIAN communities, see Walking Softly and listen carefully: Building relationships with Tribal communities and A guide for AIAN communities

Justice

Justice means that the selection of participants in research is fair, and requires that the benefits of research are equal to the burdens of research. The principle of justice includes:

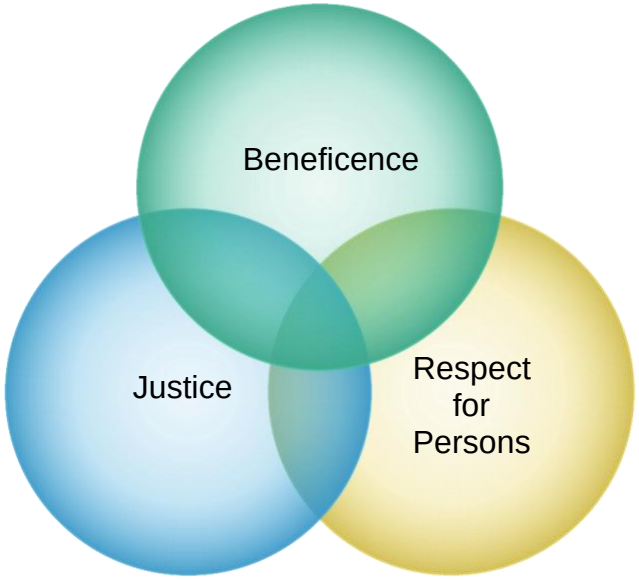
- Procedural justice: Procedures are fair and non-exploitative.
- Distributive justice: Those who experience the risks should also experience the benefits.

Justice means that people or groups of people with similar circumstances or characteristics must be treated similarly. The principle of justice is violated if only one person or group was exposed to risks of harm while others receive the benefits of science. In the past, many drug studies were tested with white males only, when women and people of color may have responded differently and could have been helped by being involved in the study. The principle of justice would also be violated if a drug tested on poor people was only available to rich people because it was so expensive.

The concept of justice becomes more complicated in different cultures and situations. Justice and equal treatment concerns can come up at any stage of the research process. It is important for researchers to consider how the groups they wish to study might perceive what is being done and to the possibilities of harms. As a researcher, you must seek to understand the science through the eyes of the people who are impacted by the study.

Balancing the Three Belmont Principles

It is possible that the three Belmont principles can conflict with each other. For example, in applying the principle of respect for persons, researchers may assume that prisoners should not participate in research because they may feel pressured into joining the study. However, under the principle of justice, prisoners should be included in research studies so that knowledge can be gained about the conditions and lived experiences of prisoners.



The ***Belmont Report*** states that no principle is less important than the other. As a researcher, think about each research project separately, while upholding all three principles to the best of your ability. In AIAN communities, be aware of ethical principles within the tribal or urban AIAN community setting where the research takes place. These principles must be balanced throughout the research project.

Summary

Even though research can contribute greatly to the health and improved living conditions of AIAN communities, several ethical research violations have been committed under the authority of the United States government as well as by academic researchers. In response, the federal regulations were adopted, including the Common Rule (Subpart A of 45CFR 46). These regulations were based on findings from the Belmont Report, a document summarizing how research with people must be conducted. It includes three ethical principles: ***Respect for Persons, Beneficence,*** and ***Justice.***

Section 3. What is Human Subjects Research?

Learning Objectives:

- Explain the definition of research
- Explain the definition of human subjects
- Understand what may not be human subjects research

In this section we define what is considered ***research*** and who are considered ***human subjects.*** A human subject is the term for someone who participates in research. Finally, we discuss which types of investigations may not be human subjects research.

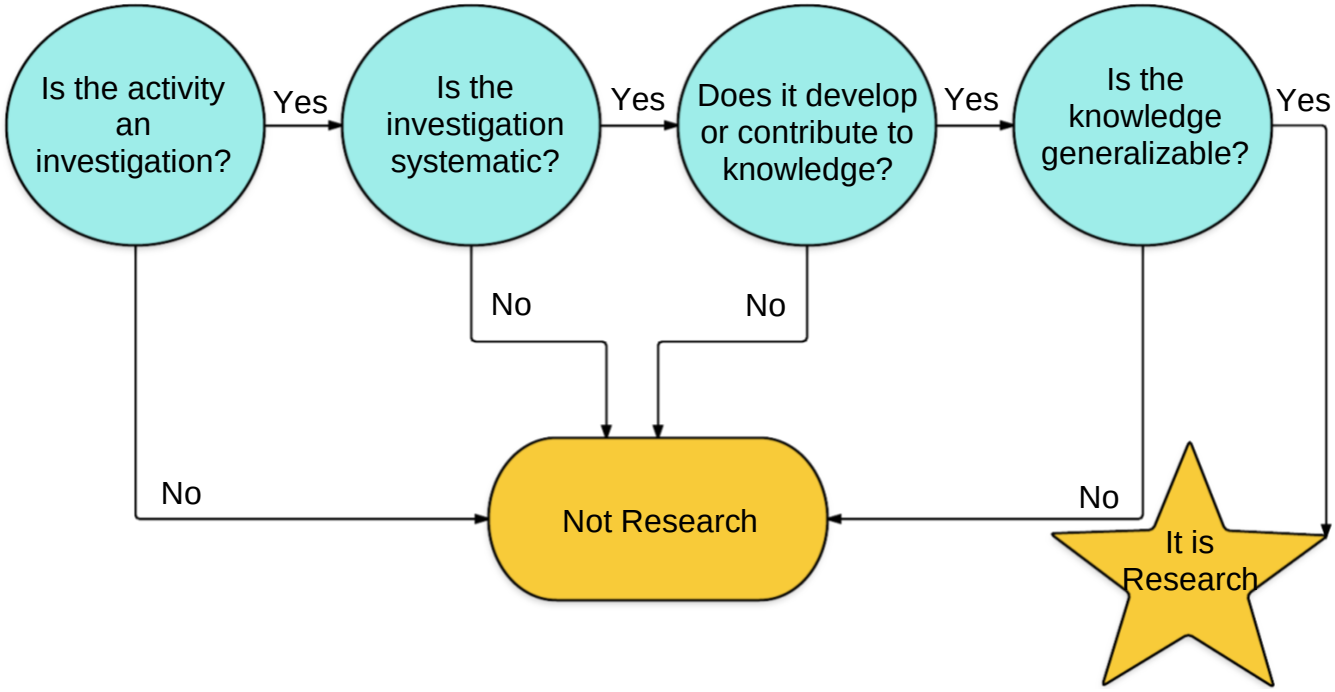
What is Research?

Federal regulations define research as a systematic investigation designed to develop or contribute to generalizable knowledge. An ***investigation*** is a search for facts, and a detailed or careful examination of those facts. ***Systematic*** means following a specific identified approach to the investigation, based on a system, method, or plan. A ***systematic investigation*** is designed to develop or contribute to knowledge by following that plan.

- ***Designed:*** The activity has a predetermined purpose or intent.
- ***Develop:*** To form the basis for a future contribution.
- ***Contribute:*** To add to what has already been done.
- ***Knowledge:*** Truths, facts, and information.

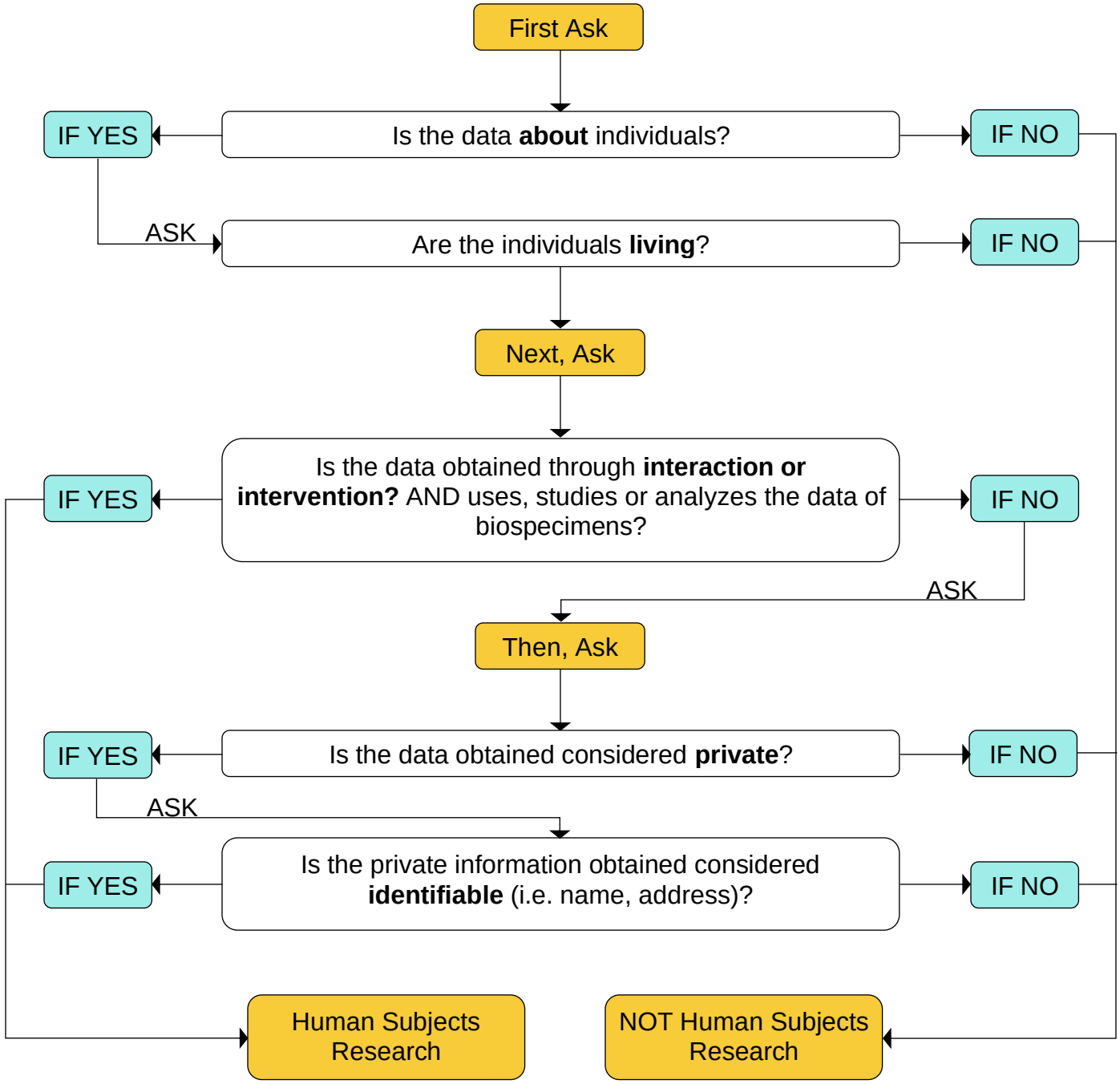
Data are facts, characteristics or information collected by the researcher and used to analyze the results of a study.

A study that will contribute to generalizable knowledge is designed so that the data and conclusions apply more broadly beyond the individuals studied, and beyond a specific time or location.



What are Human Subjects?

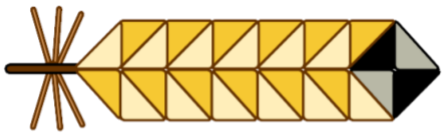
After determining if the project is considered research, you must ask if it involves ***human subjects***. A human subject is defined as a living individual about whom an investigator conducting research obtains **1)** data through intervention or interaction with the individual AND uses, studies, or analyzes the information or biospecimens; or through **2)** identifiable private information or biospecimens. Answering the questions in this chart will help to determine if a study involves research with human subjects.



What type of research may be EXEMPT from federal (IRB) oversight?

In general, the following types of studies may not be considered human subjects research and may be "exempt" from federal oversight. However, state and tribal laws might differ depending on your location and the location of your study. It is important to check your local university, tribal, or health review boards to know for sure.

Organizations or institutions often conduct studies to improve the quality of their services. This is a form of program evaluation called quality improvement. Program evaluation requires discussion with an Institutional Review Board (IRB) responsible for protecting human research subjects. Distinguishing program evaluation from research can be very challenging even to the most experienced professionals in human subjects protections.



Many tribal members view deceased individuals, their stories, and their belongings (otherwise known as their data) as sacred, and as retaining human subjects protection in like manner to data obtained from a living individual.

Tribes may require that biologic specimens are returned to the community at the end of the study to respect cultural beliefs.

At a minimum, researchers who are interested in including data from AIAN people or communities must thoroughly investigate how to meet community standards of research.

Studies That Are Exempt

- Data collected for school, departmental, or administrative purposes, such as an internal program evaluation.
- De-identified data or specimens, only if they cannot be linked to individuals.
- Information gathering interviews about products or policies rather than people.
- Case histories that are published or presented at a meeting or conference only if it describes the clinical features and the patient is not identified, the treatment is not meant to test a hypothesis, and it is not generalizable.
- Biographical research involving a living individual where the content is not generalizable.
- Course-related activities designed only for educational or teaching purposes. Data is collected as part of a class assignment and is not intended to be used outside of the classroom.

What Does Community Engagement in Research Look Like?

When a tribal or community organization becomes engaged in human subjects research, they must obtain IRB review for the research.

Engaged in Research: A community or community organization becomes engaged in human subjects research when its members, officials, or employees:

- Intervene or interact with a person for research purposes. For example, they administer an intervention, conduct a survey or interview, or obtain informed consent.
- Manipulate the environment (such as changing lighting or having a social interaction).
- Obtain, receive, or possess identifiable private information.
- Act as a representative of the research, such as a research staff member.

Not engaged in research occurs when a community, organization, or one of its members:

- Provides services that will not be for research-related recognition or publication privileges.
- Provides services that are typically performed for non-research purposes.
- Does not administer any study intervention being tested or evaluated under the protocol.

Not engaged in research occurs when a community member acts as a consultant on research and provides:

- Information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials), but does not obtain consent for the research or act as representatives of the researchers.
- Information about contacting investigators for information or enrollment.
- An opportunity for prospective subjects to give permission for researchers to contact them.

Summary

Human subjects research is a systematic investigation that leads to knowledge that can be applied across populations. It involves living individuals where the data is obtained through intervention or interaction with the individual, or through collecting identifiable private information. Making the decision about whether the project meets the definition of human subjects research can be a challenge. Consulting with your IRB or ethics experts can help in determining whether the project is research and if it needs to be reviewed by an IRB.

Section 4. Institutional Review Board (IRB)

Learning Objectives

- Summarize the purpose of an Institutional Review Board (IRB), its authority, and its membership
- Know when research may be Exempt from the Common Rule
- Describe the types of IRB review: Expedited and Full Board review

Introduction

Once it is determined that the study meets the criteria for research with human subjects, it must be reviewed by an Institutional Review Board (IRB). The Common Rule governs research that is conducted on human beings and requires a review of proposed research by an IRB.

Purpose of an IRB

Institutional Review Boards (IRBs) are official committees that review research procedures to make sure participants are respected and protected. This section will describe the IRB's role in protecting research participants and assessing risks and benefits in the research. IRBs are governed by the ***Common Rule***. Although it is not written for researchers, you should know the rules to write the IRB application and to obtain IRB approval.

The ***Common Rule*** describes:

- What research must be reviewed;
- Who must review it;
- What questions should be addressed during a review;
- The kinds of review that need to take place during the life of a project.

Code of Federal Regulations (45 CFR 46)

The CFR lays out the rules regarding human subjects research. Federal Code referred to as The Common Rule is describe in Subpart A. Subpart B describes protections for Pregnant Women, Fetuses and Neonates; Subpart C protections for Prisoners; and Subpart D describes protections for Children.

Authority of an IRB

The CFR establishes and grants authority to IRBs to oversee the research activities relevant to the protection of participants' rights and welfare. An IRB can:

- Approve and disapprove research.
- Require changes to proposed research.
- Conduct continuing reviews.
- Observe or verify changes.
- Suspend or terminate approval.
- Observe the consent process and the research procedures.
- Develop procedures for handling noncompliance.

- Provide continue review of ongoing research within 12 months of the approval date.
- Unless an IRB determines otherwise, continuing review of research is no longer required for studies that meet the criteria for minimal risk.
- Although federally funded research protections must be followed, tribal law passed by the official governing body of an American Indian or Alaska Native tribe may be applicable and provide additional protections for human subjects.

Types of IRBs

IRBs can be based within tribal nations, tribal epidemiology centers, universities, tribal colleges, and hospitals. In some cases, there can be more than one IRB review for a study. Sometimes if a tribe does not have an IRB, or to allow for the research to take place in a timely manner, tribes may delegate review authority to one IRB.

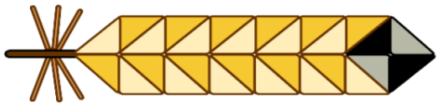
An IRB review, even by a tribal IRB, is not the same as seeking permission from the tribe or community to conduct research. In some cases, there can be more than one IRB review needed. In national studies, if the research activity is being conducted on tribal lands, permission should be obtained. Obtaining both community review and IRB review shows respect, helps to ensure ethical research, and strengthens the relationship between the researcher and the community.

Community review and permission may need to be obtained from:

- Tribal coalition
- Tribal council
- Community health committee
- Elder groups

IRB review may be obtained from:

- Tribal institutional or research review board
- Urban or regional Indian health board
- Indian Health Service IRB (national or regional)
- University, research or medical center IRB
- Tribal epidemiology centers (epi centers)
- Any combination of the above



If research takes place on tribal lands, the university and the tribal IRB may review and approve the research.

If research activities (i.e. focus groups, surveys) take place within tribal lands, the research falls under tribal jurisdiction, or if the analysis includes tribal identity, the research must be approved by the tribe.

When a research project involves more than one institution (“cooperative research”) a single IRB must be used. There are two exceptions.

1. When tribal law requires tribal IRB review.
2. When there is “a compelling justification for the exception,” that the use of a single IRB is not appropriate for the particular context.

IRB Committee Membership

The IRB is an independent committee made up of at least five members who have backgrounds related to the project needing approval. For example, a member from an AIAN community who has a background in reviewing or working on research projects might be a good fit to review research that takes place in Native communities.

Membership must include:

- At least one member from outside the institution or tribe.
- Members from different races, genders, and cultural backgrounds.
- At least one member whose experience is mainly scientific.
- At least one member who is knowledgeable or experienced in working with the vulnerable population.
- If the research includes a vulnerable population, a member from this group or an advocate (for a child or prisoner) must be on the committee.

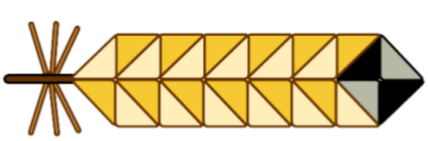
IRBs may also include consultants with specific expertise that may not be available through their board membership. An official at a university or from a tribe may deny permission for the study to take place (overrule an IRB approval) even though the IRB approved it. If an IRB reviews but does not approve a study, then the study cannot take place.

What Must Be Reviewed?

If your project is research and includes human subjects then an IRB must review the study to determine if it falls within one of three categories.

- ***Exempt*** - The ***Federal Common Rule*** identifies six categories of research that may be eligible for ***exemption*** from IRB review.
- **Expedited review** of research (no greater than minimal risk) meets one or more of 9 federally defined categories, and can be reviewed by the IRB Chair, or one or more experienced IRB members designated by the Chair
- ***Full board review*** (reviewed by full meeting IRB members).

The type of review is determined by the level of risk. Studies that meet the criteria for ***minimal risk*** are those in which the research risks are not greater than risks participants experience in everyday life or when they receive routine



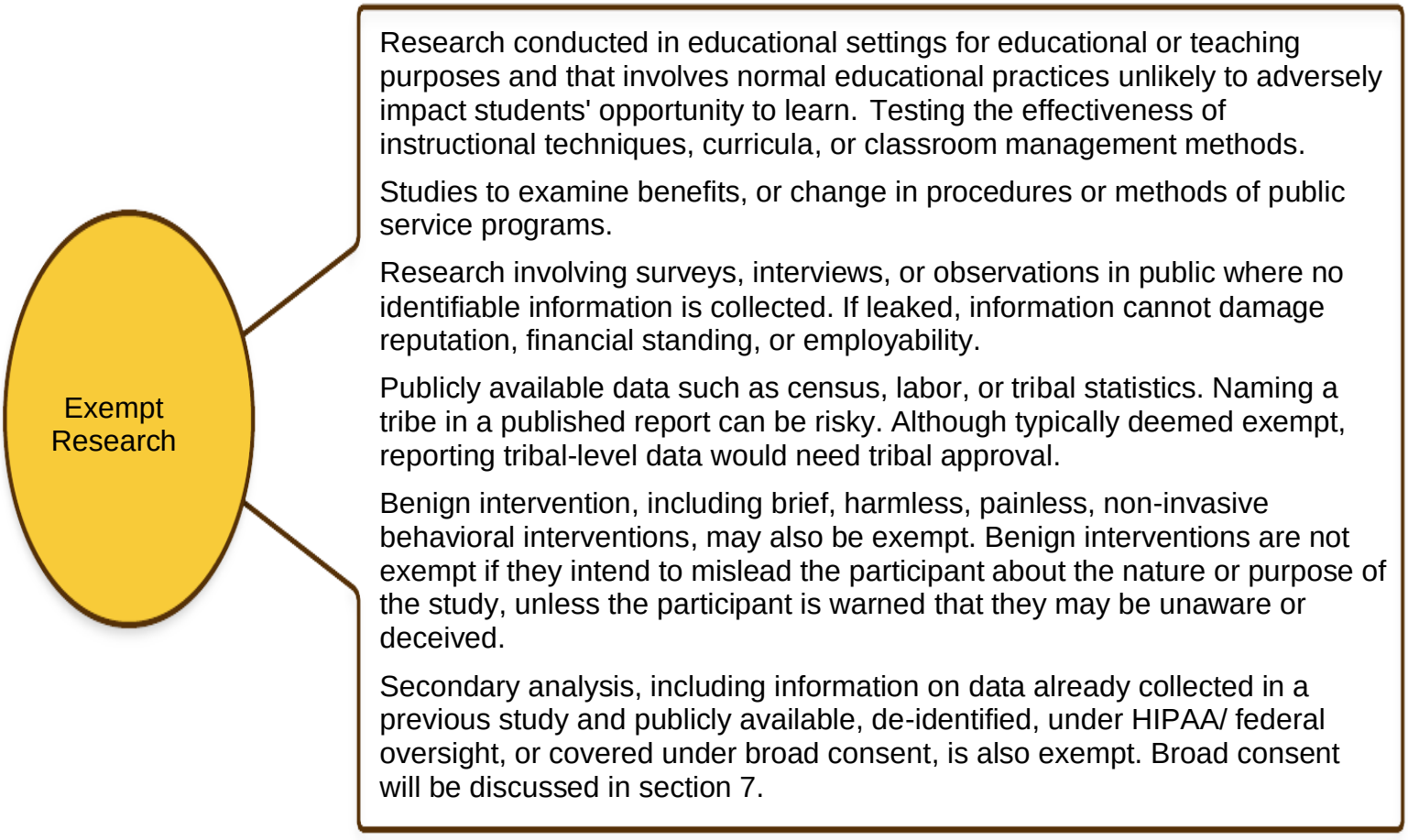
In some tribal or academic IRBs, regardless of the level of risk, all research is required to go through a full board review. The purpose is to promote greater communication and collaboration between the research team, the IRB, and the community.

This is one example of how tribal research review boards may impose different requirements to meet community research standards.

physical or psychological exams or tests. The IRB, researchers, and community boards may work together to identify potential harms and level of risk.

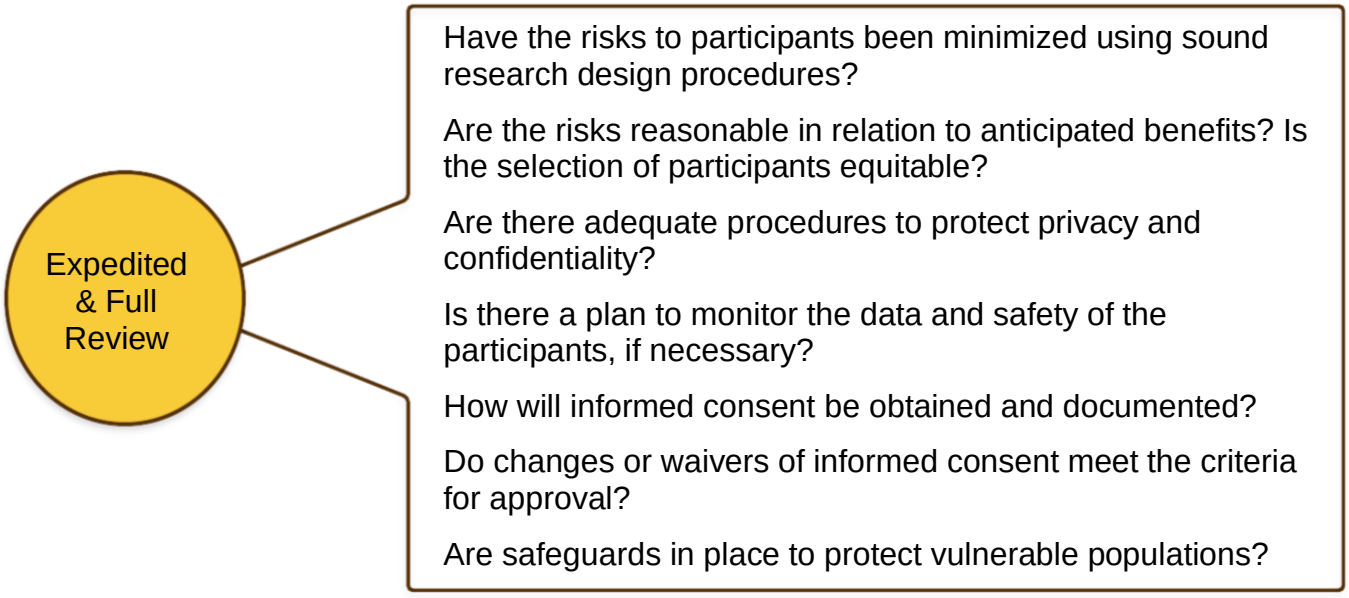
Research that may be Exempt

Research may be ***exempt*** from the Common Rule requirements if all of the research activities meet one or more of several categories. State and tribal laws differ, so it is important to check with local university, tribal, or regional review boards. There are six categories often used by social and behavioral researchers.



Review Criteria for Expedited and Full Review

The IRB will decide the type of review based on the type of risk and specific type of research being proposed. Review criteria for expedited review and full board review are similar. Expedited and full board reviews both ask:

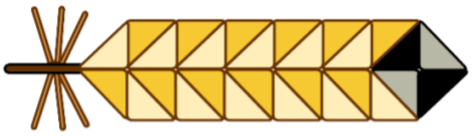


IRBs can request changes and, following approval, can specify the next review period (extend or shorten it). There are two considerations in determining the approval period.

- Level of risk.
- Adequacy of protections that are in place.

Modification: The Research is Approved, but Changes are Needed

Although academic and community-based researchers do their best to design the “perfect” study, changes are usually required. When any changes occur, whether it is a new team member who will have access to private identifiable data, or a change in the recruitment procedures, the IRB must be notified. When a change is required, it is referred to as a ***modification*** to the study procedures.



IRB Reporting Requirements include:

Written procedures for reporting unanticipated problems involving risks or harms to research participants.

Problems not previously identified in the IRB application.

Additional review or record keeping required by tribes or community organizations.

Status reports requesting renewal, before the approval expires.

IRB may also require reporting of journal articles, abstracts, or presentations.

Summary

An IRB reviews and approves human subjects research. They also make sure the research meets the federal regulation requirements. Types of IRB review include exempt, expedited, and full review. Researchers must be familiar with the rules for each type of review so their research meets the regulatory requirements. Tribes, tribal colleges, and the Indian Health Service may also have IRBs that require research review if their populations or resources are part of a study. It is important to consult with these review boards to make sure your project meets the requirements of the AIAN community.

Section 5. Risks and Benefits from Research

Learning Objectives

- Define “Minimal Risk”
- Assess the difference between the chance of risk and the severity of risk
- Understand what is meant by benefits from research studies

Introduction

This module describes how to examine the risks of harm and potential benefits that might occur from your research project. We provide definitions of risks and minimal risks. We also describe the difference between the chance and the severity of risk. We include cultural considerations specific to AIAN communities, and examine ways to think about study benefits.

What are Minimal Risks?

Every human activity carries some risk, but some activities are much riskier than others. ***Risk*** is the chance of losing something of value such as physical health, mental or emotional wellbeing, social status, or financial standing. In research**,** risk refers to situations in which there is a chance that there will be a harmful outcome. ***Minimal risk*** refers to the harms that may occur during ordinary encounters in everyday life or routine medical or psychological tests.

The ***level of risk*** refers to the chance that harm may occur and the severity of that harm. A harmful event that is very rare is no more risky than a minor harm or inconvenience that can occur often. For example, there are two recognized risks when someone drives a car to a grocery store. First is the risk of not finding a parking space (small chance), and the other is getting in a serious car accident while driving to the store (very, very small chance). Both are minimal everyday risks.

Chance is used to describe the ***probability***, or ***likelihood***, that something might occur during research.

This may seem unbalanced – that the risk of injury can be thought of as minimal everyday risk similar to the risk of not finding a parking space. This is the difference between the chance of the event occurring and severity of the event. If the chance is small but the risk is large, or the risk is small but the chance is often, then the balance between the two are similar.

Risk of harms may include:

- Group or individual social stigma.
- Psychological or emotional distress.
- Public disclosure of private information or misuse of data.
- Physical risk (rare in social behavioral research).

Risks are specific to time, situation, and culture. The chance that a harm may occur and the severity of that harm are based on a judgment people make. Here are some examples of different risks of harm.

Group Harm

When AIAN populations are the focus of a study, the group or tribal community as a whole may be at risk of harm. For example, the public reporting of research on individuals at risk for substance abuse or HIV may be culturally insensitive and could stigmatize the tribe. Knowledge of specific AIAN populations and cultural sensitivity are essential to identify, assess, and minimize research risks.

Psychological or Emotional Distress

A researcher studies generational differences in coping among adults who experienced abuse as children. The information is collected anonymously so there is no link to the participants. The most likely risk is that some participants may experience psychological or emotional distress.

Risk Varies by Situation

Consider a study that is testing a program designed to help adults and teenagers reduce binge drinking. Buying alcohol products in the U.S. is illegal for persons under 21 years of age. For adults, however, it is a health hazard, but not an illegal activity. Thus, the assessment of risk for teenagers will be different because it is an illegal activity for teenagers.

Many AIAN communities use traditional tobacco ceremonially as a medicine.

Assessing the Difference between the Chance and the Severity of Risk

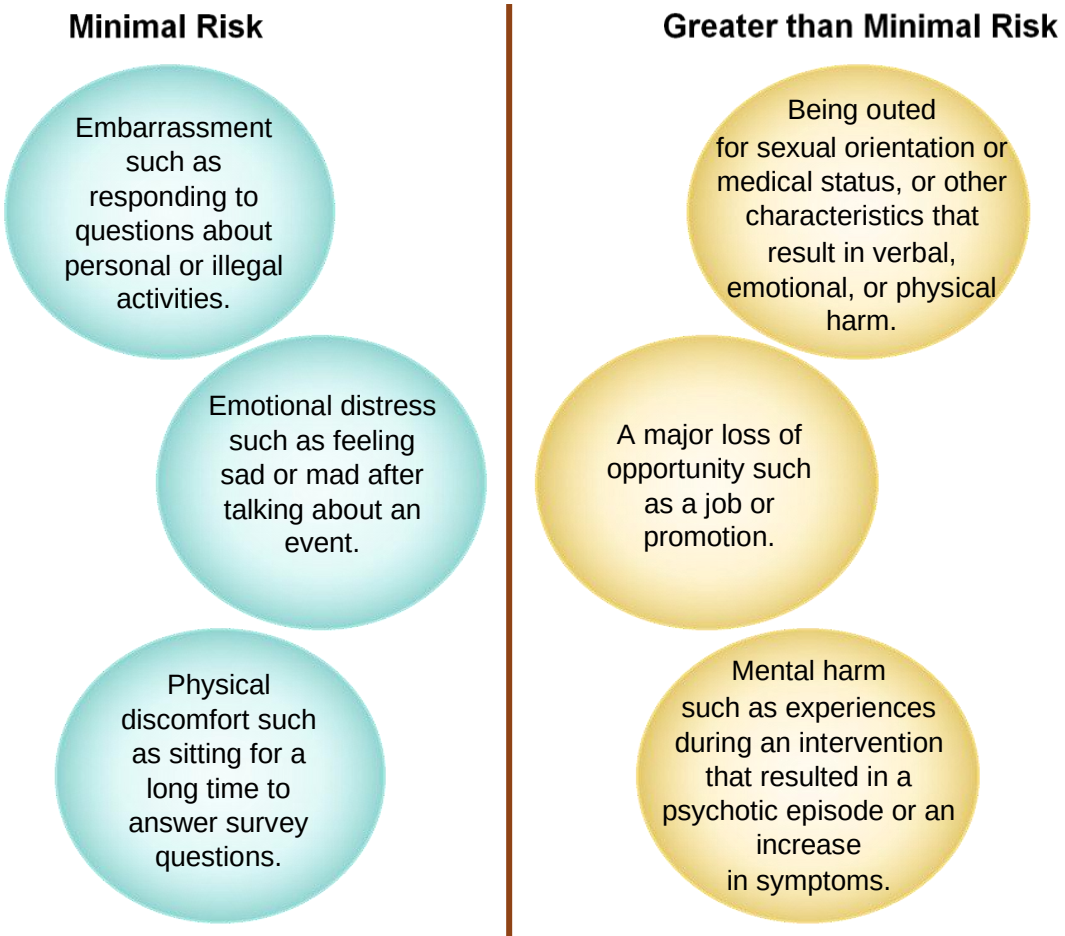
It is important to really think through the assessment of possible risks and bring in the perspectives of community members, researchers, and IRBs. There are four considerations in assessing risk.

- Identify the potential harms posed by the research activities.
- Determine the severity of the potential harm.
- Estimate the chance of the harm occurring.
- Compare the chance of each potential harm with the chance of harms equal to a similar severity and chance of occurrence.

Assessing risks can be clouded by our own experiences and perceptions. Risks that are familiar to the reviewer are often viewed as low risk even when they may be far riskier than unfamiliar risks.

Severity of Harm

Negligible and small harms are considered minimal risk. Harms greater than minimal risk should be balanced with major benefits. Here we provide examples of harms that might be considered minimal risk, and harms that might be considered greater than minimal risk.



Benefits

As with risks, the assessment of benefits can be affected by our judgments and experiences. As a researcher, you should look to many sources when assessing benefits. You should look to community members, science, and the literature. Moreover, without a potential benefit, no risk is permitted.

What is a Benefit?

Benefits may occur at many levels. Research can benefit a participant, a community, the researcher, and society. Research is conducted to determine if it will have an impact on society. Although research often intrudes into the lives of individuals, participants may not always receive a direct benefit from research.

Consider the benefits from a study among 200 Native men and women with depression. The study included peer support groups and connecting participants to community resources. The researcher worked with community members to design a culturally-grounded, evidence-based intervention that included community values, local resources and counselors, and worked with local schools and service agencies. The study received tribal approval and provided services across a large reservation. The table highlights possible benefits from this study.

Examples of Benefits from a Research Study				
	Participants	**AIAN Community**	**Researcher**	**Society**
Relationship	Ties to the research team and local providers.	Ties and trust developed with academic researchers.	Partners with a community in research activities.	The relationship is extended to improving research in other tribal communities.
Knowledge	Participants have an opportunity to contribute to knowledge that can improve the lives of AIANs in the future.	The community gains additional knowledge about the strengths and vulnerabilities of its members.	Learns how to design depression research that reflects the lived experiences of AIANs.	Academic researchers improve training in how to study depression in AIAN communities.
Treatment	An opportunity to receive an experimental treatment that may improve health.	An opportunity to learn what types of interventions are helpful to community members.	The intervention is successful for an AIAN community.	The program is shared to treat other AIANs.
Materials or Resources	Compensation to participate in the study.	Access to the intervention manual, & salaries are covered for counselors.	Academic and community researchers apply for grants and continue their research.	The culturally grounded prevention program is proven to be effective.
Training Opportunities	Participants learn about the research process.	Counselors trained in an intervention & training provided for future counselors.	More research experience.	Models for national training for AIAN communities.
Empowerment	Engagement in a study that can benefit their community.	Prestige & strengthening partnerships across agencies.	National reputation enhanced and increased funding opportunities.	Increased ability to serve AIAN communities.

Summary

Balancing risks and benefits requires consideration of situation, time, and culture. It requires input from many stakeholders. The benefits of the research are often in the value of the knowledge to be gained for the AIAN population and in the contributions to the community and society in general. Benefits of research to society may justify conducting social and behavioral science research that poses little or no risk to the participant. Risks must be minimized to the extent possible and must be balanced with the benefits, consistent with a sound research design.

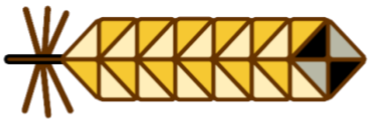
Section 6. Ensuring Confidentiality and Managing Risk

Learning Objectives

- Understand the difference between ***anonymity***, ***privacy,*** and ***confidentiality***
- Identify ways to assure privacy, confidentiality, and to minimize risk
- Identify laws that protect and limit the ability to ensure confidentiality
- Identify risks to confidentiality related to different study designs

Difference between Privacy, Anonymity, and Confidentiality

Perhaps the primary source of risk in social and behavioral research is information obtained that could harm participants or tribes if shared outside of the research setting. Three concepts often confuse new researchers: ***privacy*** (which is about the person), ***anonymity*** (about the data) and ***confidentiality*** (also about the data). **Data is *anonymous*** when the researcher cannot link the data to any unique identifiers. **Data is *confidential*** when the researcher can link the data to unique identifiers, but has procedures in place that makes sure no one outside the research team can make that link. This section provides a brief discussion of all three concepts and ways to minimize the risk of a ***breach in confidentiality***.



Protecting the identifiers of AIAN communities (i.e., name of the tribe or geographical area) is just as important as protecting the identifiers of a participant. For example, many Alaska Native villages are very small, so stating a geographic area or town may serve as an identifier.

Anonymity

Anonymity means that no ***unique identifiers***, such as names, addresses, IP addresses, phone numbers, social security numbers, driver's license numbers, or video or audio recordings are collected. As an example, if the information in survey research is only collected once and no unique identifiers are collected, then participants may be more likely to participate and more forthcoming in their responses. To help keep persons from being connected to the study, a researcher could:

IP addresses are unique numbers assigned to every computer that is connected to the internet. Identifying information such as name, city, state, and exact geographical coordinates can be accessed through IP addresses.

- Provide a number for participants to call if they want more information.
- Request a waiver for documentation of informed consent. IRB regulations generally require a written, signed consent form. However, if the signed form is the only form linking a participant to the data, then a waiver may be granted. All consent information is still provided in a cover letter, informational sheet, or verbal script (also referred to as oral consent). See section 7 on Informed Consent for more information about waivers.

Anonymous data collection poses little to no informational risk for the participant. There is a difference between just being identified as being in a study, and having all of a person's data connected to their identity. Anonymous data is when there is no link from a person's identifiers to their data.

Privacy

Privacy is about the person. It refers to a person's "degree of control of the access someone has to them and their information." Including a person's information in a study could be an invasion of privacy if a person did not agree to share information with the researcher, if the data is identifiable, or if the person has not consented to the ways in which the data will be disseminated. Privacy concerns can affect the willingness of a person, tribe, or community to participate in research if recruitment or consent is done in a group. It can affect the individual's willingness to give honest answers or to stay in a study. False or partial responses, or high levels of participants dropping out can result in poor research. If a town is very small, the researcher may have to meet the participant in another area of town or a neighboring town to protect privacy. Privacy concerns are subtle, can vary by culture, and may not always be immediately understood by researchers or IRBs.

What you think is private might not be what other people think is private. Some ceremonies that take place in public are sacred and should not be recorded.

Communities and cultures look at privacy differently. What is okay in one community might not be okay in another.

Private vs. Public Behavior

Watching and recording ***public behavior*** is not considered research with human subjects. As a researcher, how can you tell the difference between what people do in public and what people do in private?

Private information includes:

- Information about behavior that occurs in a context in which a person can reasonably expect that no observation or recording is taking place.
- Information which has been provided for specific purposes by an individual and where the individual can reasonably expect it will not be made public (such as a medical record).

How you act at home is private information. Private behavior can also happen in a public area. For example, parents taking their children

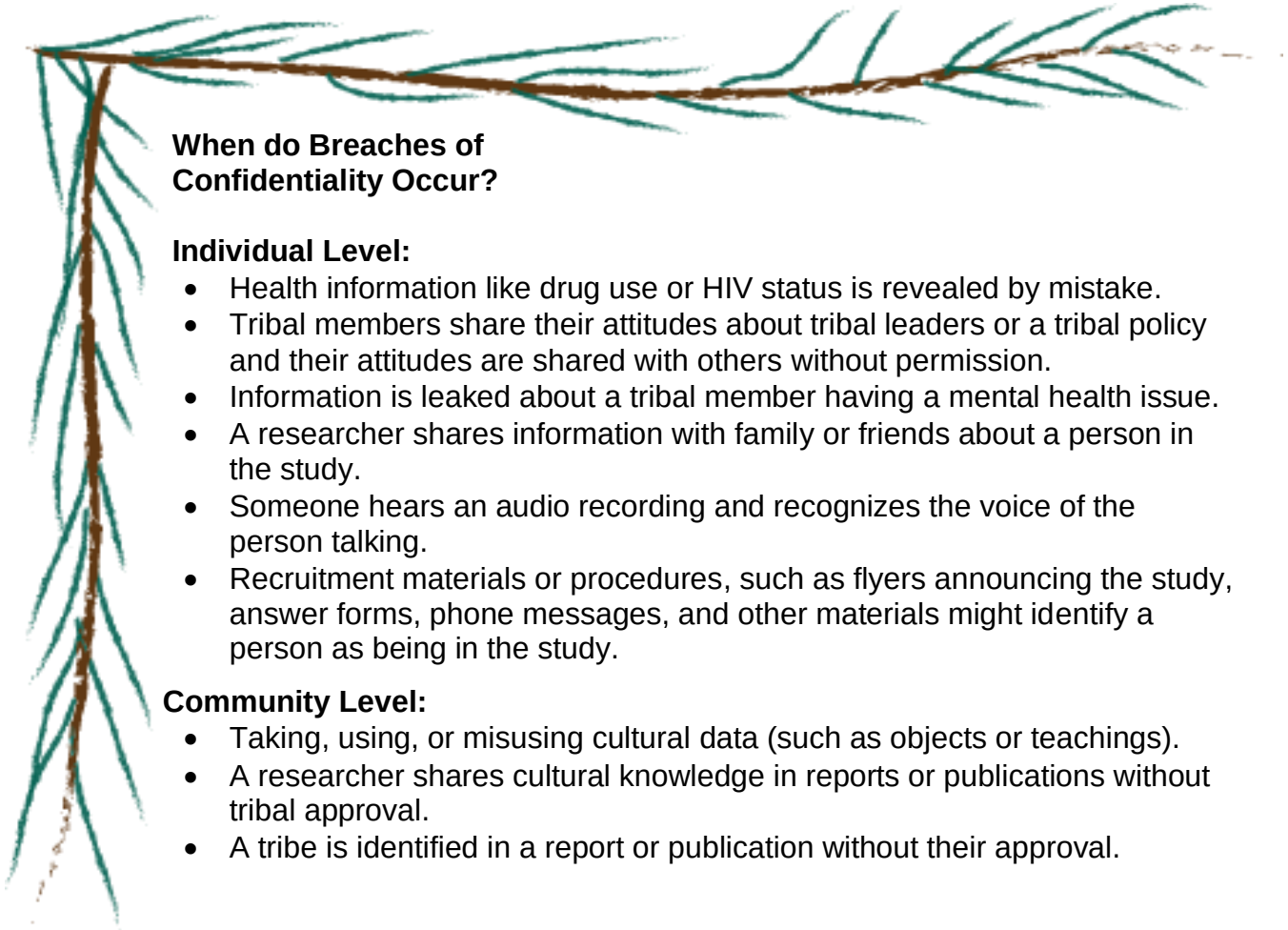
to a park would probably feel like their privacy was violated if researchers made tapes of their playing children without first asking for their permission to take part in the study. How you act on a street corner, a shopping mall, or even in a restaurant is often considered ***public information***. Social media may also be considered public – though there is yet to be consensus on the topic. Given the interest in using social media to promote or conduct research, researchers should take care to make sure participants agree to their level of social media involvement. You will need to work with your IRB and community to establish a plan for social media considerations.

Protection from Invasions of Privacy

Researchers are expected to learn about individual as well as community privacy concerns. You can seek information from community advisory boards, community research review boards, service providers, or members in the community who work with the population that the study hopes to include. Obtaining the most appropriate review and approval can help ensure the research meets community privacy and confidentiality norms and expectations.

Confidentiality

A breach of confidentiality (exposure of identifiable data to others) can result in the loss of a job, reputation, or can even stigmatize a group of people. Adequate precautions with the data must be in place and described in detail in the consent form.



When do Breaches of Confidentiality Occur?

Individual Level:

- Health information like drug use or HIV status is revealed by mistake.
- Tribal members share their attitudes about tribal leaders or a tribal policy and their attitudes are shared with others without permission.
- Information is leaked about a tribal member having a mental health issue.
- A researcher shares information with family or friends about a person in the study.
- Someone hears an audio recording and recognizes the voice of the person talking.
- Recruitment materials or procedures, such as flyers announcing the study, answer forms, phone messages, and other materials might identify a person as being in the study.

Community Level:

- Taking, using, or misusing cultural data (such as objects or teachings).
- A researcher shares cultural knowledge in reports or publications without tribal approval.
- A tribe is identified in a report or publication without their approval.

Risks to Confidentiality Related to Different Study Designs

Different study designs present different risks. There are a number of ways to reduce the risks so that they are no more than minimal risk. Below we provide a few examples of how different studies introduce different risks and how those risks can be minimized.

Focus Groups: People who take part in focus groups might share information about other participants with someone outside of the group. There are steps you can take to reduce risks before a group begins. Inform participants:

- The researcher cannot promise that the information will be kept confidential.
- To pledge not to share anything said within the group with people outside of the group.
- To keep the information confidential
- Not to disclose any information that might damage their reputation.

Longitudinal study: A study that measures behavior before and after an intervention and then requires follow-up at a later date to see if the intervention worked. If the unique identifiers are breached it would link the person to their information. To protect the unique identifiers:

- Destroy all identifying information (of the participants and the tribes) as soon as possible.
- Use a secret code (numbers and letters) for identifying information.
- Keep the secret code and answers in separate locked locations.
- Destroy codes as soon as possible.
- Use and protect computer passwords.
- Add additional passwords for the files containing the data.

Studies on stigmatizing or illegal activities: Studies involving HIV status or illegal drug use should take extra precautions.

- Never store coded data and the key linking data to identifiers on the same computer.
- Obtain a government ***Certificate of Confidentiality***. This is discussed later in this chapter.
- Limit the personnel who have access to the data.

Laws that Limit Confidentiality

Maintaining confidentiality in research can be complex. There are several factors to consider when understanding what may limit study confidentiality.

Tribal and State Reporting Requirements: Researchers must inform participants of any information that will not be kept confidential and must be reported. Tribal and state laws have reporting requirements for researchers.

- Suspected child or elder abuse and neglect.
- Some communicable diseases, such as a sexually transmitted infection (STI) or HIV.
- The intent to harm oneself or others.

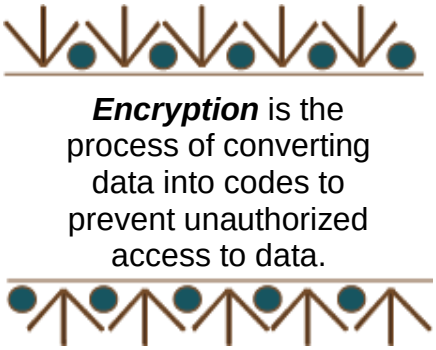
Consult with your IRB, tribal authority, and state laws regarding reporting requirements that may apply in the area where the research is being conducted.

Federal Guidelines: There are specific federal laws that protect school records (Family Educational Rights and Privacy Act (FERPA) and private health information (Health Insurance Portability and Accountability Act (HIPAA). Studies that collect school or medical records must follow the appropriate regulations.

International Privacy Laws: Researchers conducting research in different countries must learn what kinds of privacy and confidentiality laws apply to the study site.

Tribal communities in border regions also require special considerations. If the tribal community stretches across state or country boundaries, the laws offering confidentiality protections or requiring certain types of reporting may be in conflict. As a researcher, you must learn how to work within and across these boundaries.

Laws that Protect Confidentiality



There are a few legal documents that can protect confidentiality issues in a study. The first, a Certificate of Confidentiality, is a legal document that protects research data, including unique identifiers, from being subpoenaed in a court of law. It also emphasizes keeping data ***encrypted*** or in an anonymous form.

Certificates of Confidentiality (CoC):

- May be granted for studies collecting information that, if disclosed, could damage a participant's financial standing, employability, insurability, or reputation.
- Will protect identifiable research information from compelled (forced) disclosure by subpoena in civil, criminal, administrative, legislative, or other proceedings at the federal, state, or local level.
- Are issued by the National Institutes of Health (NIH).
- If the research meets the health related mission of the NIH, then a CoC may be obtained for any research, regardless of funding.
- Similar certificates may also be issued, such as a Privacy Certificate through the National Institute of Justice (NIJ).

Types of Protections under Certificates of Confidentiality	
Protected	**Not Protected**
Substance abuse and illegal behaviors	Child abuse
Sexual attitudes, preferences, or behaviors	Threat of harm to self or others
Genetic information	Some communicable diseases
Psychological health information	Participant's voluntary disclosure

Data Use Agreements

Many tribal and academic partners develop ***data use agreements***. These agreements are legal contracts, which may be enforced by a court of law. They detail rights to data ownership, data sharing, data use, access, storage, and rights to review reports and manuscripts prior to publication.

Many AIAN communities have their own governments and their own laws requiring how researchers should protect people's names and information. It is very important that you respect tribal law and community cultural views.

While planning the study, researchers should discuss data ownership, data use, publications, and dissemination activities with tribal representatives.

Determine confidentiality risks by:

- Thinking about the chance and severity of risk that may be caused by the research.
- Figuring out if the chance and the severity of risk changes by the research context (situation, place, and time) or study population.

Reduce risk by:

- Asking culturally relevant and appropriate questions that the AIAN group understands.
- Respecting the person's privacy and keeping names and information confidential.
- Making sure all research staff are trained in respecting privacy and confidentiality.
- Limiting the information you ask to participants (keep it specific to your research question).

Summary

Two of the most important tasks researchers face are protecting the privacy and confidentiality of participants and their communities. Violations of privacy and confidentiality can occur during recruitment, data collection, and during the publication of results. Researchers must be familiar with procedures that best protect participants' rights.

Section 7. Informed Consent

Learning Objectives

- Describe the consent *process*
- Know the content that must be provided to obtain informed consent
- Identify ways to make the consent content understandable
- Explain when consent content is waived
- Know how to document the consent process and when documentation may be waived
- Apply strategies to make sure that participation is voluntary

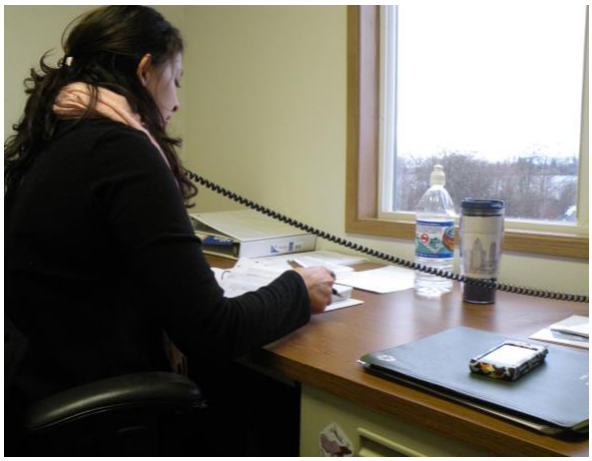
Introduction

Honoring the principle for respect for persons includes giving individuals a chance to consider participating in research. This process is called informed consent. During the informed consent process the researcher tells individuals what they may expect as a participant in the study. The researcher also obtains the person's voluntary agreement to participate. Informed consent is an ongoing process between a researcher and an individual.

- ***Informed*** means the person is provided with a reasonable amount of information to make a sound decision about their participation.
- ***Consent*** refers to the very clear and affirmative agreement to be in the study.
- ***Process of consent*** means after the initial agreement, the researcher continues to check in with the participant about their decision to remain in the study.
- ***Individual*** may mean a legally authorized representative, if the study participant is not able to make decisions for themselves.
- ***Legally authorized representative*** may include a person, court of law, or other body that has designated decision-making making authority through a legal or other authority recognized in the jurisdiction where the research takes place.

In this section we discuss the consent process, the content (information) that must be provided, and when that content can be waived. We then discuss the different ways to document the consent process, and when the documentation may be waived.

Consent as a Process: Building a Relationship



Consent is a process of building a relationship between the research team and the participant. The process includes how the information is presented and the kind of information provided. Informed consent does not happen one time. Instead, it happens throughout the life of the study. In other words, consent is a process, not a form. Researchers do not consent participants. Rather, consent is an action or decision by a person.

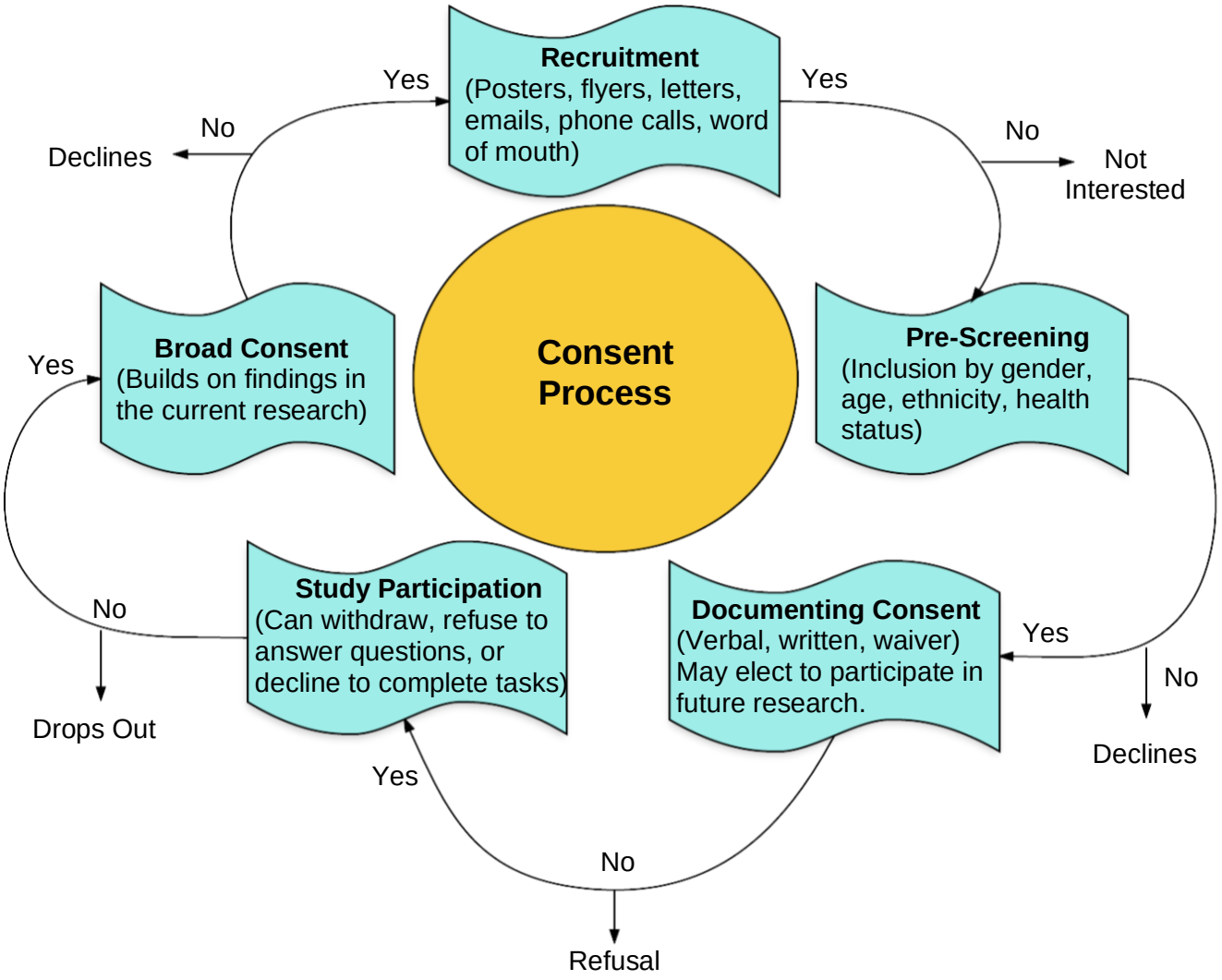
The consent process begins with Recruitment, which is when someone first hears about the study. Recruitment materials, such as fliers, email messages, newspaper ads, and phone calls must be truthful, non-coercive, and must not highlight monetary or other compensation.

Consent continues through pre-screening. Pre-screening is asking questions to determine if the study will be a good fit for the participant and if they meet the criteria for study participation. It provides an opportunity to tell a person about the study so they can decide if they would like to participate. During the pre-screening a person may be asked to give personal or sensitive information to determine eligibility. If the person is eligible, a researcher may ask for permission to proceed with the questions.

The next step is to document the participant's agreement to be in the study. The Documentation of Consent is important because it provides a record of the agreement or understanding made between a participant and the researcher. It includes content needed to make an informed choice about being in the study.

It is at this point that a participant will begin Study Participation, such as taking a survey, receiving an experimental or control treatment, or participating in a new type of prevention program. The informed consent has made clear to participants that they can refuse to answer questions, decline to complete a certain task, or can withdraw entirely from the study at any time. These are all ways to allow participants to change their minds. These steps emphasize the voluntary nature of their participation.

Broad Consent. Researchers may offer prospective participants the choice of consenting to the use of their personal identifiable data or biospecimens for secondary research without future consent.



Content that Must be Provided to Obtain Informed Consent

The consent statement should inform potential participants that the study is “research.” It should describe the purpose, length of participation, procedures, risks/ discomforts, benefits, and alternative procedures/treatment (if applicable). It must be easy to understand. The statement should not be written like a legal document. General and additional content requirements are listed.

General Requirements

- Explain what will be involved in the study, why it is being conducted, about how many people will be in the study and length of participation.
- Ensure the consent process does not ask participants to give up any of their legal rights. Asking someone to give up their legal rights is called ***exculpatory language***.
- Describe the possible risks, discomforts, or worries that may occur.
- Describe the benefits or good things that might happen. If there are no clear benefits for the participant, explain what will be learned, and how it will be useful to the community or other groups.
- Let the participant know if there are other treatments or opportunities available outside of the research.
- Describe how their information, data, or biospecimens will be kept confidential.
- Describe how the information, data, or biospecimens will be stored and the duration of storage.
- Discuss whether and when individual or aggregate findings will be shared with participants.
- Provide contact information if a participant has questions, breaches of confidentiality, violations of privacy, or injuries from the study.
    - If people with a question cannot call or e-mail someone, there has to be another form of contact, such as a local and available person on the research team.
- Ensure persons understand that participation is truly voluntary, free from pressure to participate, and includes:
    - Declining to participate will not result in a penalty or a loss of benefits that the participant may already have.
    - The participant can quit the study at any time.
    - There are no penalties for declining to participate.
    - The participant has the right to skip any questions for any reason.

Additional Requirements (When Appropriate)

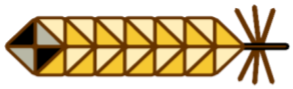
- Sometimes study procedures are added to a treatment. Participants should be told if research study procedures, treatment, or assessment is added to standard practices.
- Most states and tribes require researchers to report suspicion of child or elder abuse, or injury to others. Participants must be told about these requirements.
- A statement that the research may involve unforeseeable risks.

- Describe situations where researchers may end a persons' participation without their consent.
- Possible financial costs to the person for being in the study.
- Describe what happens if a person decides to withdraw from the study.
- The option of Broad Consent: The choice of consenting to the use of personal identifiable data and biospecimens for secondary research.
- If biospecimens are collected whether they will be used for commercial profit and whether the participant will receive any portion of these profits.
- If the study includes whole genome sequencing.

Participants will receive information about new research findings that could affect their health or change their decision about staying in the study.

Making Consent Content (Information) Understandable

As a researcher, you must use words, terms, and concepts that are understood by the people who will be recruited. If there is a misunderstanding, a person may join the study, then feel harmed or deceived because it was not what they expected. Dropping out or not returning to the study may result in poor research findings. It is best to help participants understand expectations and why the research is being conducted before they begin the study. The table shows several ways to help make the consent statement clear.



In many of our AIAN communities, IRBs ask researchers to use an 8th grade reading level.

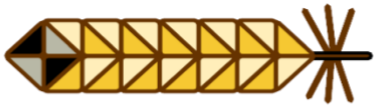
Technique	Explanations
Pretest the consent statement	Test with people similar to those you will be recruiting. Ask them to read the statement and tell you what they think it says in their own words, then revise the statement based on what they have shared.
Reading level	Adjust the reading level to fit the population that is being recruited.
Time to consider	Provide the person with enough time to consider if they want to be in the study. Invite them to come back the next day or next week with their decision. For some Native people considering participation in certain types of studies, it may be appropriate to invite the person to discuss participation with their families.
Best interest	Encourage the person to make a decision that is in their best interest.
Translate	Use the primary language of the participant or provide a translator.
Provide a private place	A private place will remove pressure from onlookers. It may also provide a safe space to ask questions.
In their own words	Ask the person to describe the study and their role in the study in their own words.
Provide a short quiz	If it is an online survey, a short quiz at the end of the consent statement may be given to verify understanding.
Provide an advocate	An advocate may help the person feel more comfortable and help them understand the process or ask questions.
Space for children	Provide a supervised space for children so the adult can focus on what is being asked.
Consider cultural norms	Learn about cultural norms and ways to encourage open and honest consent.
Train the recruiter	The recruiter should be comfortable presenting the consent statement.

Continued participation	Check in about continued participation. When calling or meeting with a participant, ask if they are still interested or if they have any questions or concerns.

Common Uses of Waivers for All or Part of the Consent Content

Waivers are not intended to preempt any applicable Federal, state, or tribal laws that require additional information to be disclosed in order for informed consent to be legally effective.

Partial waiver or alteration of informed consent: This means that the consent process would either leave one of the required elements of consent out, or it would be changed to meet the needs of the study. For example, in a study that requires ***deception***, researchers may ask the IRB to provide permission to leave out a description of some parts of the study.



Deception is providing false or incomplete information to mislead participants. Deception has a negative history among AIAN communities and may not be appropriate.

The use of deception or not telling the truth about the details of a study can sometimes be approved if it is essential to the science and social value of the study**.** Deception has been benfitial in research and has helped reserachers to learn about important topics. For example, a participant may be told that a study is about perception of visual experience, when in fact it is about peer pressure. If people know that they are being watched, they may change what they do, thus changing the result and making the findings false. Deception may require the IRB to waive elements of the consent procedures. If deception is used, then debriefing may be done, so long as debriefing does not do more harm than participation itself.

Waiver of Consent Content (Information)

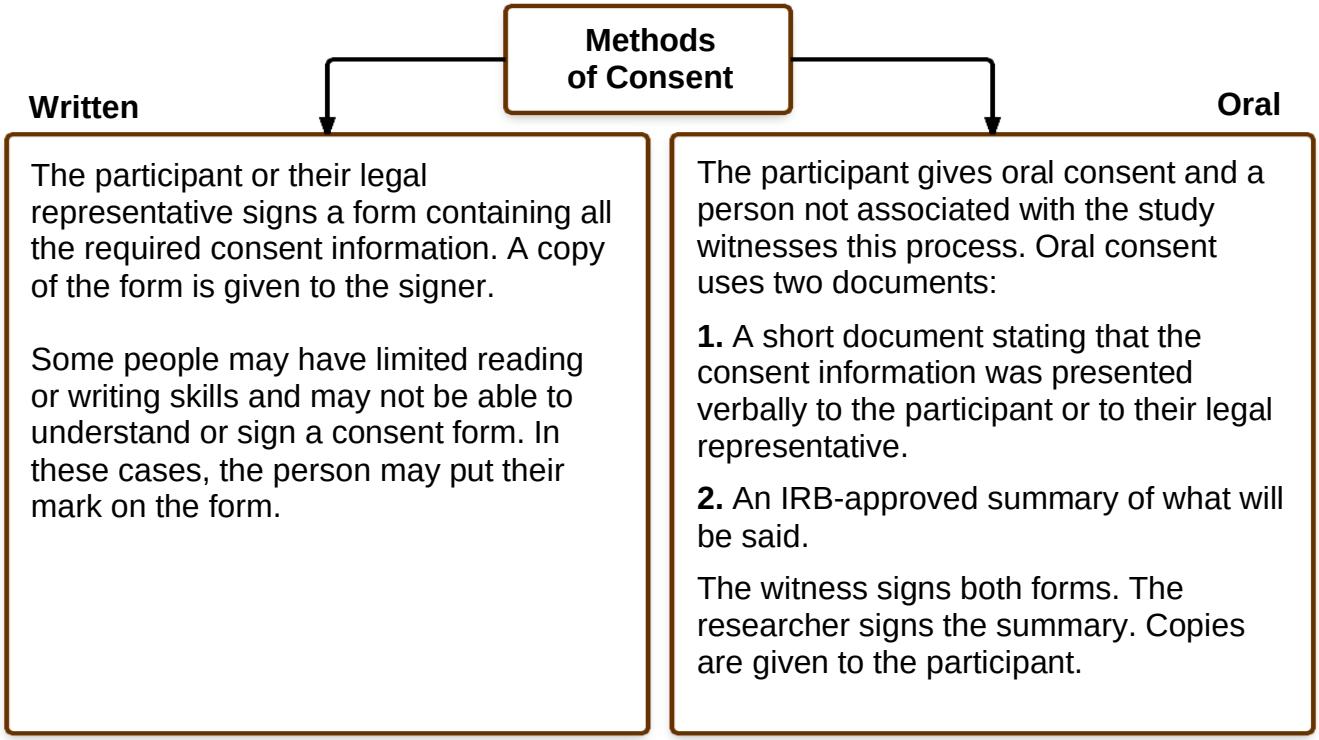
Federal laws allow IRBs to waive the required consent content by leaving out some or all of the information given to participants. The change can be granted only if these four conditions are met:

1. The research involves no more than minimal risk.
2. The waiver will not affect the participants' rights and wellbeing.
3. The study likely cannot be done without the waiver. If the true purpose of the research was shared, it may influence how the participants respond.
4. Participants will be provided with additional information after participating in a study. After a person has participated, the researchers will discuss the real purpose of the study in detail. This provides the participant an opportunity to change their mind about including their information in the study findings.

Usually, guardian permission is necessary for a child to participate in research. If the four conditions are met, then the IRB may grant a waiver of the parent's consent. Sometimes other regulation may change the conditions. Please refer to the Vulnerable Populations section for more information.

Documenting the Consent Process

Documentation of consent provides a record that the consent process took place. Documentation can be through a written or oral consent agreement. Video and audio recordings may be used to assist participants who understand but may not be able to speak or write English. Written consent is most common.



Requirements for Clinical Research

Clinical research trials test medical device, drug, or other new medical or behavioral interventions. For these type of studies a copy of the informed consent document must be available online at a specified federal clearinghouse within 60 days from the close of participant enrollment.

With approval from federal funding agencies, investigators may remove confidential commercial information from these posted consent documents. This may be particularly important if the documents include protected cultural or other tribally-specific information that must be kept private.

Waiver of Written Documentation

Documentation of the consent process is not always required. However, waivers of documentation are not waivers of the consent process itself. Documentation may be waived under two circumstances:

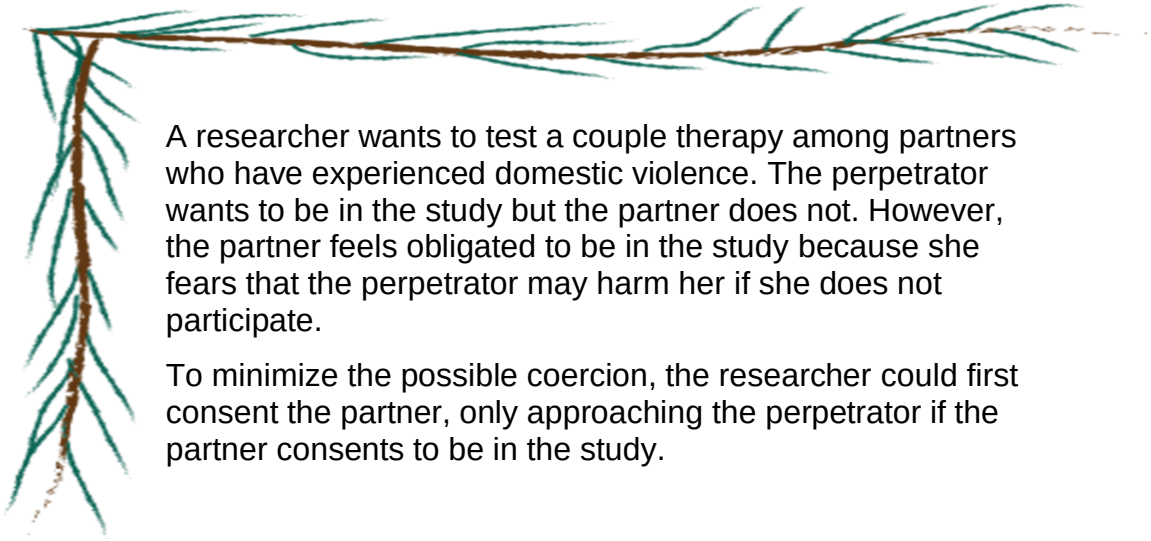
- The main risks are related to a breach of confidentiality about a person being in the study, AND the consent document is the only record linking the person to the research. For example:
    - Research about women who have left abusive partners.
    - A study about illegal activities.
- Study participation presents minimal risk of harm to the participant and the research involves no procedures requiring consent outside the context of participation in a research study. For example:
    - An in-person interview about environmental education.
    - Prescreening for a study by phone

When the documentation is waived, the IRB may require researchers to offer participants information about the study in writing such as an information statement. An information statement looks and reads just like a consent form but the person does not sign it.

Strategies to Ensure Free Choice

Making sure that the consent process is understood is important. It is also important to ensure ***free choice***, meaning that the consent to be in a study is completely voluntary. There are two major influences that researchers must work to reduce in order to ensure free choice.

Coercion involves a threat of physical or psychological harm to the individual if they do not agree to be in the study. Here is an example of coercion and one way to minimize it.



A researcher wants to test a couple therapy among partners who have experienced domestic violence. The perpetrator wants to be in the study but the partner does not. However, the partner feels obligated to be in the study because she fears that the perpetrator may harm her if she does not participate.

To minimize the possible coercion, the researcher could first consent the partner, only approaching the perpetrator if the partner consents to be in the study.

Undue influence is more subtle than coercion, such as being asked to participate by an authority figure that the participant knows and respects, or if the reward for being in the study is excessive or unfair. Consider these undue influences and ways to minimize them.

Acknowledging that tribal leaders approve of a study and that the tribe encourages members to participate may make the person feel as though they must participate because of their leaders' influence.

To minimize undue influence, researchers will need to remind the person that it must be their own individual choice to participate in the research. Researchers will also have to promise participants that their data will be kept anonymous or confidential. Transparency and detailed explanations of how the data will be protected and who will have access to it will be very important.

If a teacher conducting a study offers extra credit to her students for participating, and there is no other way to earn extra credit, then this is considered undue influence. The same applies to doctors who ask their own patients to be in a study they are conducting.

To minimize undue influence, it is okay for the teacher or doctor to announce the study or hand out information, but consent should be obtained by somebody who is not in a position of authority over the person being recruited.

Summary

Informed consent is an ongoing process that includes certain ways of sharing information and documenting the process. There is specific content that is required for informed consent. To make an informed consent decision, participants must have free choice and be able to understand the consent materials. This may mean making sure the consent materials meet the participants' needs related to language, physical limitations, and culture. Documentation of the consent process is often required. Documentation can be written, obtained orally, or obtained through audio or video recording. The documentation of consent may be waived if it meets the two conditions under 45 CFR 46.117.

Section 8. Vulnerability

Learning Objectives

- Define vulnerable populations
- Identify federally recognized vulnerable populations
- Describe the protection of vulnerable populations
- Describe four levels of risk for prisoners and other vulnerable groups.

Understanding who is vulnerable and in which situations is not always clear. A vulnerable person is someone who may be more susceptible to research risks, to coercion, or who may not be able to provide fully informed, voluntary consent. In this section we discuss the groups who are especially vulnerable in certain types of research. We also discuss the protections that are in place for these groups.

Who is Vulnerable?

There are three vulnerable populations specifically defined by federal regulations. They are ***pregnant women and fetuses (subpart B)***, ***prisoners (subpart C),*** and ***children (subpart D).*** Information on pregnant women and fetuses as a vulnerable group is discussed in the CITI Biomedical training curriculum. We will discuss children in a later section. In this section, we focus on situations that may increase vulnerability for groups. We also discuss prisoners as a vulnerable population.

A ***prisoner*** is any person involuntarily held in federal, state or tribal penal institutions. This also includes people in hospitals or treatment facilities under court order.

Depending on the context of your research, other groups may be considered vulnerable. There are many factors that determine whether a person or a group is considered vulnerable. There are also different ways in which a person or group might be considered vulnerable. In these three tables we describe six types of vulnerability, an example for each type, and possible solutions for protecting a person or group experiencing the vulnerability.

Individual or Personal Vulnerability			
Type	**Definition**	**Example**	**Protections**
Cognitive Vulnerability	Inability to understand, make a rational choice, and give informed consent choice because of illness, injury, age, or because someone is in a state of crisis.	A researcher wishes to conduct a study with individuals with early onset Alzheimer's disease.	Determine if the individual has the capacity to independently consent. Use clear and simple language. Ask the person to tell you in their own words about the purpose of the study, what they would be expected to do, and about the possible risks.
Health Vulnerability	A person is invited to participate in research because they have a certain health condition.	If there are no other treatments, they may believe this is their "last hope."	Make sure the person is told about other treatment options. If no other treatment is available, they must fully understand the risks as well as the benefits of participation.

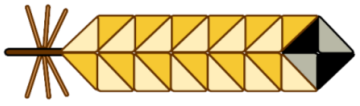
Relationship Vulnerability			
Type	**Definition**	**Example**	**Protections**
Vulnerable to Authority	Any relationship where a person has power or authority over another.	Students may fear they will get a lower grade or fail a course if they choose not to participate. Prisoners may fear they will not get parole or lose access to certain privileges.	Inform the person that participation will not affect their grades, privileges, or parole. Clearly state what information can be kept confidential and what information must be reported.
Deferential (Respectful) Vulnerability	Sometimes being respectful, eager to please, or not wanting to offend makes it hard to say no to the researcher.	A person agrees to participate out of respect for the person asking, not because they truly want to participate.	The researcher must acknowledge their standing in the community and make sure that the participant separates the researcher's role from their decision. The participant must understand that their relationship will not be affected by their decision. Another option is to have someone other than the researcher conduct the consent process.

Environmental Vulnerability			
Type	**Definition**	**Example**	**Protections**
Allocation (Resource) Vulnerability	When the incentive (i.e. childcare, housing) for participating is so attractive that it makes the person participate when they would not otherwise. This can be seen as undue influence.	A single mom does not want to participate in the research, but agrees because she is offered 6 months of free child care for participating.	Select compensation that is fair and equitable given the participant's situation.
Infrastructure Vulnerability	When institutions and the research team do not have the skills or tools to protect data and people.	A research team works in a space where computers that store data are used by others who are not involved in the study.	Encrypt the data, store data off line, secure computers from breaches in confidentiality, and create data sharing rules. Obtain a Certificate of Confidentiality to protect data from subpoena when appropriate.

Protection of Vulnerable Populations

In the Risks and Benefits section, we described possible risks from research, including inconvenience, emotional or physical harms, social harms, economic harms and legal harms. Along with these risks, there are additional considerations when conducting research with vulnerable populations.

- A person belonging to a vulnerable group must be allowed to choose if they want to participate in research. Tribal members must be allowed to choose, even if the tribe has already said yes. If a tribe says the research cannot take place on their lands, researchers cannot approach tribal citizens on tribal lands. However, if the research takes place nationally or regionally and a tribal member sees an announcement and wants to participate, they have the right to choose.
- The study must be relevant to their lives. Research with an AIAN community must benefit AIAN people.
- A group cannot be chosen for research as a matter of convenience.
- The research data must be protected to the fullest extent possible. This is especially important when collecting sensitive data such as HIV status, reasons why someone is in prison, or a person's experience with trauma.



In situations or cultures where women are not considered autonomous or self-governing, the researcher must respect cultural norms. However, the researcher must also work with the community to create a confidential process for these women, regardless of their status in the community.

IRB Review of Research with Vulnerable Populations

There are additional IRB considerations when reviewing research with vulnerable populations. At least one member of the IRB must be from the group being studied, or a representative with appropriate background and experience to serve on the IRB committee.

- Exempt review is often not allowed.
- Expedited review is often allowed but in some AIAN communities it is discouraged.
- Full review is not always required but is preferred in some AIAN communities to ensure protections.
- Written documentation of informed consent can be waived only by the IRB. If waived, participants must be clearly provided with the required information (unless waived).

Approving Research with Prisoners

Prisoners are vulnerable because they have lost their freedom and they are under control of the prison system, which impacts their capacity for consent. As a group, prisoners risk being studied simply because they are a population of convenience. Researchers knew where they would be located, often for many years. Prisoners also lived under controlled conditions that can make it easier to conduct research. Historically, it was acceptable to use prisoners as research participants to test medicines and devices without regard to the risks, benefits, or their rights. Today, there are special regulations.

- A representative for prisoners must be involved in the IRB review of studies involving prisoners.
- Incentives are allowed, however, they cannot be so excessive that prisoners agree to research just to receive the incentive.
- The risks involved in the research are equal to the risks for non-prisoner participants.
- Procedures for the selection of participants within the prison are fair to all prisoners. They must be selected randomly from the group of available prisoners who meet the requirements of the study.
- Information is presented in language that is understandable.

If a participant becomes imprisoned during the study, then research activities must stop immediately. The participant can rejoin the study once they are no longer incarcerated.

An exception is when it is in the best interests of the participant to stay in the study, such as being in a clinical trial involving medicine that the participant needs. Then the IRB must re-review this study using the review criteria for prisoners.

- Each prisoner must be clearly informed in advance that participation will have no effect on his or her parole.
- Adequate provisions are made for follow-up examination or care. Each prisoner should be informed what provisions have been made.
- Federally funded research with prisoners may require additional federal consultation and approval.

Summary

There are situations that place certain groups in vulnerable categories. You should be aware of these risks to vulnerability and put into place the necessary protections. Although research with prisoners was highlighted in this section, many of the same considerations for ensuring informed consent, assessing risk and benefits, and protecting privacy and confidentiality apply to all vulnerable populations. Working closely with your IRBs and research partners will help ensure the principles of respect for persons, beneficence, and justice for vulnerable populations are upheld throughout the research process.

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Section 9. Children in Research

Learning Objectives:

- Define who is considered a child, parent, and guardian
- Define child assent and parent or guardian permission
- Understand the four levels of risk for children and when research may be exempt
- Know when parental permission and child assent can be waived
- Explain research requirements concerning use of school records

Regulations

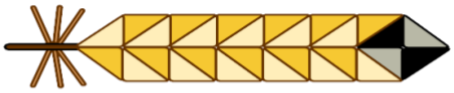
The specific rules governing research with children is Subpart D of the code of federal regulations. All federal research with children funded by Department of Health and Human Services (DHHS) requires that research follow Subpart D of the regulation.

Mandatory Reporters

Researchers are considered ***mandatory reporters*** in most tribes and states. They are required to report suspicion of child abuse or neglect. Each state is different, so IRBs and researchers must know state laws and include what applies for their state. Parents and older children must be informed that if they disclose abuse or neglect, the researcher may be required by law to report it.

Who Is Considered a Child?

Children (or Minors) are persons who have not reached the legal age for consent to treatments or procedures involved in research. In most states and tribes, minors are individuals who are less than 18 years old. Age of minor can differ by culture, tribe, state, and can be different in international research settings. It is necessary to consult local law to confirm the legal definition of a minor.



In some situations, biological parents allow other relatives to raise their children. In these cases, the adults are given decision making authority but do not have legal parental custody. However, for all purposes, such as in school, medical, or cultural situations, they act in place of the biological parents and are recognized by the community as the legal guardians.

Who Is Considered a Parent or Guardian?

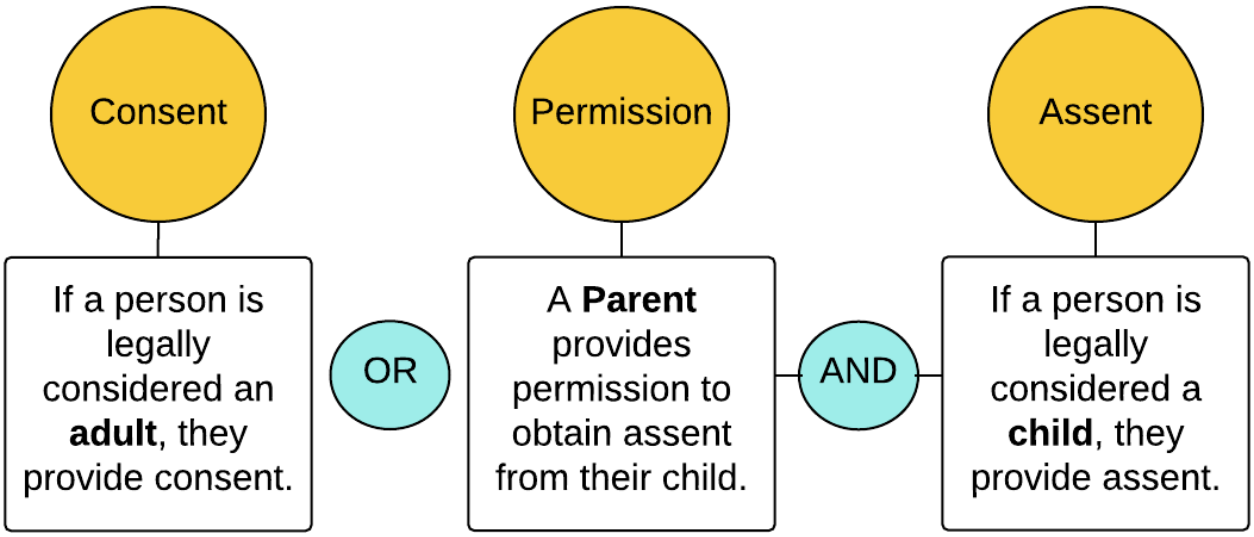
A ***parent*** is the child's biological or adoptive parent. A ***guardian*** is a person who is authorized under tribal, state, or local law to consent on behalf of a child to general medical care.

Parent Permission and Child Assent

When recruiting a child into a study, the child gives their ***assent*** to participate. Assent refers to the child's agreement to participate. If the child does not clearly state yes, assent has not been obtained. For example, if the child starts crying or showing other resistance, you should recognize the child does not assent. The information provided for assent is different for children than for more mature youth. Mature youth generally receive study information comparable to that provided to adults. Assent is required unless it is waived by the IRB.

Even before the child gives assent, the parents or guardians must give ***permission***. Permission is the agreement of parents or guardians to allow their children to participate in research. If the IRB says that parental permission is required and the parent says no, the child cannot be asked if they want to be in the study. If permission was given by the parent but the child said no, you must respect the child's wishes. The diagram explains the differences between consent, permission, and assent.

It is common for children to be interviewed in a room separate from the parent or guardian in order to minimize undue influence.



Definitions of ***emancipated minors*** include those who are self-supporting or not living at home, married, pregnant, parenting, in the military, **or** declared to be emancipated legally by a court.

Emancipated Minors

Emancipated minors are treated as adults for all legal purposes. Emancipated minors have decision-making authority without the need for parental involvement. The situations in which minors are deemed to be totally or partially emancipated are defined by the law and may vary by culture, state, and tribal government.

Decision Making Authority

Many states and tribal governments give decision-making authority to youth who are not emancipated. These youth have decision-making capacity (mature minors), live independently, or are seeking care for individual health problems that might not otherwise receive appropriate attention (sexually transmitted diseases, pregnancy, or substance abuse). As a researcher, you should work with your IRB and consult local tribal laws to determine if youth have decision making authority for consent to participate in research without parental permission.

Children who are Wards

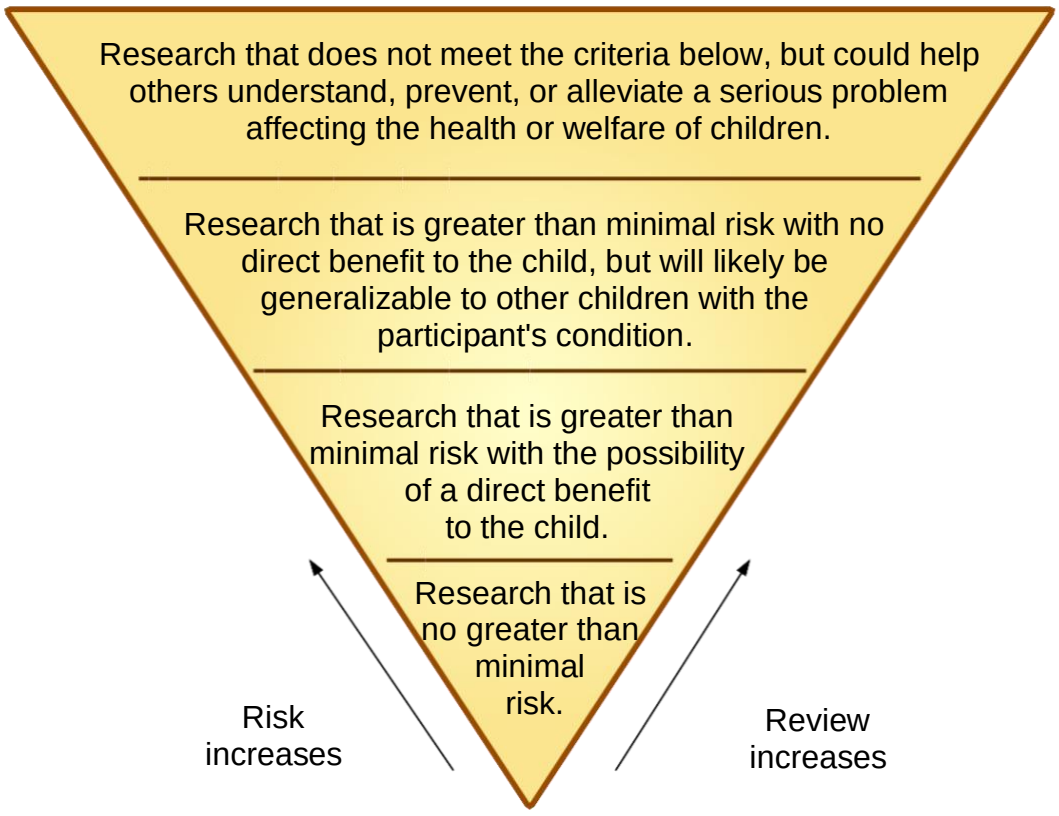
A child who is a ward of the state or any other agency, institution, or entity can participate in research (CFR 46.409). A ward is a child who has been removed from their parents' care. Wards may be children in state or tribally controlled out-of-home care, foster care, or juvenile detention. An ***advocate*** may be appointed to a child who participates in research. Research with a ward can only be conducted if either criteria are met:

1. If the research is related to the child's status as a ward.
2. If the research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.

An ***advocate*** is an individual who has the background and experience to act in the best interests of the child during the study. An advocate cannot be related to the researcher or to the organization overseeing the child's guardianship.

Four Levels of Risk in Research with Children

There are four levels of risk. When the level of risk increases and the benefits to the child decrease, additional protections apply. In the lowest two levels of review, some or all of the requirements for parental permission and child assent may be waived.



Exempt Research with Children

Research activities involving children that might meet exemption criteria include educational tests or observation of public behavior where the researcher does not interact with the children. The activities must also meet these conditions.

- The data are recorded without individual identifiers.
- Disclosure of the responses would not place the child at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

Expedited or Full Review

Expedited review is an option if the research activities pose no more than minimal risk and fall within defined Categories of Research. The categories cover a range of activities, including interviews, questionnaires, and the use of cheek swabs to collect genetic material. Some IRBs and tribal review boards have policies that require a full IRB review specifically for children.

Waivers of Parental or Guardian Permission

Parent or guardian permission can be waived if the research involves no more than minimal risk to participants, and if the waiver will not adversely affect the rights and welfare of the youth. If both of these circumstances are met, one of two waivers can apply.

Waiver of two-parent permission is where only one parent must provide permission. A waiver can be granted:

- If research is greater than minimal risk but of potential direct benefit.
- If only one parent has legal responsibility for the care of the child.
- If one parent is deceased, unknown, incompetent, or not reasonably available.

A complete waiver of parental permission may be granted:

- Permission is not a reasonable requirement to protect the youth. For example, the research includes children who have been abused or neglected.
- An appropriate method for protecting children in the research is provided.
- The waiver is consistent with tribal, federal, state, and local laws.

Passive Permission

Passive permission is when researchers assume permission has been granted if parents have not actively refused. Imagine that a form is sent home from school giving parents the option to opt out of a research study for their child. If the form is not returned, it would be considered passive permission. However, there is no assurance that the form has reached the parents, so you can never assume that a parent has given permission. This type of permission would not meet requirements for consent. The IRB would need to approve a waiver of consent in order to use passive permission.

Waiver of Documentation of Permission

The documentation of parental or guardian permission can be waived under one of two conditions.

Federal regulations do not require documentation of a child's assent.

1. The document is the only record identifying the child's involvement in the research, and the main risk would be a breach of confidentiality. If the parent wants a signed or unsigned form, then one is provided.
2. The research involves procedures for which parental permission is not normally required outside the research environment.

An IRB will determine whether and how documentation is required for a particular study. When the requirement for documentation is waived, the IRB may require the investigator to present each parent or guardian with a written statement describing the research.

Waiver of Child Assent

Sometimes, circumstances may require a waiver of child assent. To waive child assent, at least one of these three conditions must be met.

1. The capability of some or all of the minors is so limited that they cannot understand the assent process.
   - This could be due to developmental stage, cognitive impairment, traumatic brain injury, emotional delays, or other issues. This is determined by expert input and careful review across multiple stakeholders.

Children who are enrolled in Special Education might have the capacity to provide assent.

OR

2. The research is likely to provide direct benefit that is important to the health or well-being of children and is available only through the research.

OR

3. If participants are capable of assenting, all four criteria are met
   - The research involves no more than minimal risk to the child.
   - The waiver will not adversely affect the child's rights and welfare.
   - The research could not practicably be carried out without the waiver.
   - Whenever appropriate, the child will be provided with additional information after their participation.

Additional Regulations Involving Children

When conducting research in schools, you must consider issues regarding the availability of class time, school resources, and the ability to obtain parental permission. There are also federal laws that govern research in schools. In addition to the Common Rule, there is the Family Educational Rights and Privacy Act (FERPA) govern parental rights over education records and the Protection of Pupil Rights Amendment (PPRA) govern parental control over child's participation. This section will outline those regulations.

Tribal schools and Bureau of Indian Education (BIE) schools may follow federal and tribal laws that have specific requirements for research.

The Family Educational Rights and Privacy Act (FERPA)

The FERPA provides parents certain rights over their child's educational records. This includes educational records past high school. Schools must have written permission from the parent or eligible student before releasing school records. School records may include identifiable information such as religious affiliation, citizenship, gender, ethnicity, and contact information. School records also include disciplinary status, attendance, grades, test scores, and progress reports.

- FERPA does allow schools to disclose records without consent under some circumstances.
  - For example, when a school, school district, or state department of instruction initiates a study.
- Directory information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance.
  - Schools must first tell parents and students that directory information is not protected.
  - They must allow parents and students a reasonable amount of time to request that the school not disclose directory information about them.

The Protection of Pupil Rights Amendment (PPRA)

PPRA gives parents some level of control over their child's participation in survey research or exposure to instructional materials for the purposes of research. The protection applies when the research is funded either directly by the Department of Education or indirectly from the general school funds.

The protection covers eight sensitive topics that require parent or guardian permission before the information can be used for research.

- Disciplinary status, illegal, anti-social, self-incriminating, or demeaning behavior.
- Mental health of the student or the student's family.
- Sexual behavior or attitudes.
- Critical evaluation of individuals or close family members of the child.
- Legally recognized privileges held by lawyers, physicians, counselors, or spiritual leaders.
- Religious practices, affiliations, or beliefs of the student or the student's parents.
- Political connections or beliefs of the student or the student's parents.
- Income except what is required by law to determine eligibility for participation in a program or for receiving financial assistance.

Summary

Children are considered a vulnerable population. The definition of child can be different across tribal, international and state boundaries. Parent or guardian permission and child assent is often required. Under certain limited circumstances, parent permission and child assent can be waived. Also, the documentation of permission and assent is usually required, but this too can be waived under limited circumstances.

Researchers interested in conducting research in schools must consult with school administrators to determine if FERPA or PPRA apply. For students in tribal schools or Bureau of Indian Education schools, additional requirements may apply.

Section 10. Unanticipated Problems and Reporting Requirements in Research

Learning Objectives

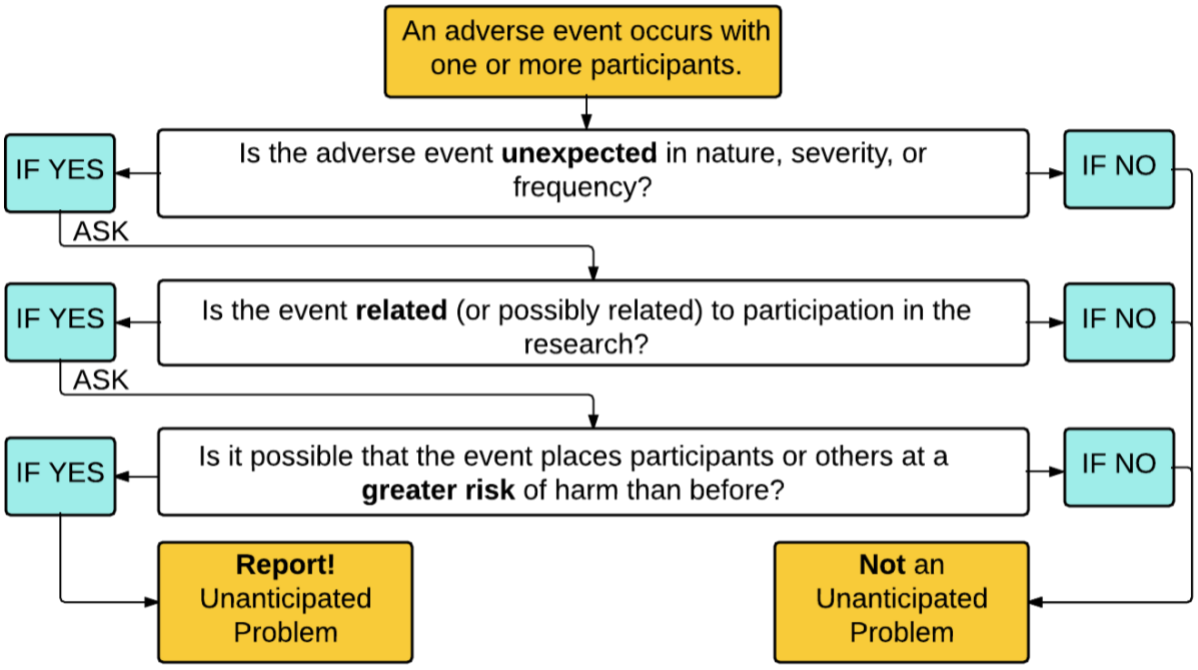
- Define unanticipated problems
- Know the reporting requirements for unanticipated problems
- Understand what IRB action may take place

No matter how much researchers prepare for studies in advance, unanticipated problems sometimes occur along the way. Researchers must report these problems promptly to the IRB(s), and to federal and tribal agencies when required.

What Are Unanticipated Problems?

An unexpected event that increases the risk of harm to research participants or others is referred to as an ***unanticipated problem***. Unanticipated problems, include any incident, experience, or outcome that meets all of the following criteria:

1. **Unexpected** (in terms of nature, severity, or frequency) considering the research procedures that were described in the IRB-approved research plan and informed consent document, and considering the characteristics of the population being studied.
2. **Related or possibly related to participation in the research** ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
3. The research places subjects or others at a **greater risk of harm** (including physical, psychological, economic, or social) than was previously known or recognized.



Reporting Requirements

IRBs must have written procedures ensuring prompt reporting of unanticipated problems. These written procedures state to whom the event is reported. Typically, this includes the IRB, tribal or institutional officials, and the department or agency head. Although there are variable time frames for reporting a problem, when a researcher becomes aware of the problem, they should contact the IRB immediately. The IRB will assess if the unanticipated problem increased risks to participants or others, and decide what course of action should be taken.

Possible IRB Actions

Actions that an IRB may take include, but are not limited to:

- Requiring modifications to the research plan
- Modifying the consent document or consent process
- Requiring that current participants be re-consented
- Providing additional information to current and/or past participants
- Requiring additional training of the researcher and/or study staff
- Reporting the unanticipated problem to federal and tribal agencies

Working Together to Address Unanticipated Problems

Sometimes, even though researchers make every effort to think through all possible problems, something unexpected occurs. The first duty is to the participant. Researchers must work with the IRB to ensure participants are protected and are receiving support to address the possible harm associated with the unanticipated problem.

The second duty is to the AIAN community. Having an accepted communication method helps in case of unexpected problems. Researchers should communicate regularly with AIAN community leaders and review boards in clear, concise ways that everyone agrees upon before the research begins. When the communication is made, the researcher should identify steps they are taking to address the issue and possible outcomes. The researcher should also inform the community of when to expect updates and ask if the community has other steps that the researcher should take to address the issue.

Building a relationship with AIAN community members early in the research can help researchers better understand the community expectations if a problem occurs. In some cases, it may be necessary for the researcher to apologize in culturally-specific ways or take other steps to remedy the issue that are unique to that community. Being open and trying to look at the situation from the community perspective can help research partners progress through these issues and build stronger relationships.

Here are two examples of reportable events and the actions that the IRB took in each situation.

A study focuses on decreasing the drug and alcohol use in teens. Survey data is collected from the teenagers and their guardians before the intervention, immediately after the intervention, and 6-months later.

During one interview, the researcher learns that the teenager is being abused. Unfortunately, the process and forms for obtaining guardian permission and child assent did not inform participants that researchers are required to report abuse. It also did not state that confidentiality cannot be guaranteed in these situations. The guardian is angry that the researchers are revealing what he considers to be private family information, and is challenging the entire research project as intrusive and disrespectful.

In this situation, the IRB may require that the researcher change their consent process and forms and re-consent each person in the study. The IRB may also require that the funder and other key-stakeholders be informed.

A study surveys middle school children about their beliefs and attitudes of their school experience, including what they think of their classes and teachers. The approved IRB application stated that when the survey is collected, the front page with the student name, classroom, and teachers' name be torn off so that only a study code number is on the survey booklet. The surveys will be stored in an office within the school. The researcher will pick them up and store them off-site. In one school, the research assistant forgot to tear off the front page. The principle found the surveys and read them, thus learning students' negative comments about the teachers. Not only were the teachers' reputations—and possibly even employment—at risk of harm, but the relationship between teachers and their students who made negative comments could be adversely affected.

In this situation, the IRB may require that the research staff be retrained, require better supervision by the research coordinator, and request a change in the protocol so that no surveys are ever stored at the schools.

For both of these reportable events, there may be additional steps that the researcher can take to address the unanticipated problem. How might the unanticipated problem impact the AIAN community and the researcher's relationship with them? Are there culturally specific ways to address the mistake?

Summary

Reporting of unanticipated problems requires researchers and IRBs to be familiar with the reporting requirements and with the elements that qualify as an unanticipated problem. It is important for researchers to be aware of their responsibility to report promptly and to know to whom they must report.

Data Sharing and Ownership Agreement

for the

Project title
(Grant "Number and Name")

between the

Tribal Nation

and the

University of Washington

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1. PROJECT PURPOSE AND SCOPE

1.1 Project Purpose: The Tribal Nation ("Nation") and Indigenous Wellness Research Institute National Center of Excellence of the University of Washington ("UW") are collaborating to plan, develop, and implement a research study about reducing PTSD symptoms, preventing substance use disorders, and preventing HIV and sexually transmitted diseases in and around the Reservation.

1.2 Project Scope: The research project, named "Name" ("Project"), involves a 5-year two-arm randomized clinical trial ("RCT") to reduce substance use and HIV risk taking among 200 American Indian men and women 16 years old or older, and living on or near the Tribal Reservation. The Project shall be conducted in accordance with 45 C.F.R. § 46 et al., along with any and all other applicable federal standards governing research on human subjects. This Agreement will be in effect from the date of signature until up to five years following the completion of the study.

1.3 Data Defined: For the purpose of this Agreement, "Data" shall mean any and all primary source information gathered in the course of the Project that contains "personally-identifiable information", as that term is used in 45 C.F.R. § 46.101, relating to the Project's participants. "Data" does not include data sets, data summaries, reports, or other academic publications where personally identifiable information has been removed. The Tribal Nation's cultural traditions, customs, history, and/or stories will never be collected or recorded during this Project, and to the extent any such information is inadvertently recorded in any way, UW agrees to immediately deliver the information to the Tribal Nation and destroy any remaining related records in UW's possession, whether in physical form, electronic form, or otherwise.

2. DATA MANAGEMENT, SHARING, AND OWNERSHIP

2.1 Data Management Guidelines: The Tribal Nation and the UW agree to the following binding guidelines for data management, sharing, and ownership:

a) *Data Ownership*: The Tribal Nation shall maintain sole ownership and control of the Project's Data. The UW and the National Institute of Health ("NIH") are hereby granted a royalty free, nonexclusive right to use the Data to develop and publish reports or other academic publications for educational and research purposes in furtherance of the aims of the Project, provided that the strict confidentiality of all Personally Identifiable Information is maintained at all times.

b) *Data Access*: Any entity other than UW, NIH, or the Tribal Nation who wishes to access, view, or use the Project Data must formally request in writing and be granted express permission by the Tribal Nation Tribal Council, and proceed through an Institutional Review Board ("IRB") review process.

c) *Data Collection*: Before any Data is collected, the existing Project Community Advisory Board ("CAB") will draft and approve an IRB application for submission and approval by the University of Washington IRB.

d) *Data Protection*: UW researchers are responsible for data collection and analysis, and for keeping all data containing personally identifiable information and their sources confidential. By signing this agreement, the UW recognizes and accepts responsibility to ensure appropriate investigator conduct in relation to the data. UW shall remove all Personally Identifying Information from any and all Data collected as a result of the Project in accordance with applicable federal, state, tribal, and institutional laws and regulations.

e) *Data Storage*: For the duration of the Project, UW will house all physical and electronic Data in secured, locked physical and electronic systems, including locked file cabinets and secure, password-protected databases on secure servers within the UW offices. UW will also maintain and keep the de-identified Project Data to the limited extent necessary to complete any study aims, reports, and dissemination activities authorized by the IRB. After termination of the Project and upon completion of the time allotted by the IRB to fulfill Project-approved publication or dissemination activities, all data retained by UW must be provided to the Tribal Nation, or destroyed at the Tribal Nation's express written direction.

f) *Data Use*: In connection with the Project, the parties agree to establish a Dissemination Committee whose function shall be to review and decide matters pertaining to the distribution and use of Data, and to the scholarly and other publication of any research results. The Dissemination Committee's membership will include the Principal Investigator ("PI") designated in the applicable Grant Approval, and at least one representative appointed by each of the following: the

Tribal Nation Tribal Council, Sacred Journey Committee , and the Tribal Nation Behavioral Health Program. The Dissemination Committee will be chaired by the Principal Investigator for the Project and be governed by such rules as the Dissemination Committee deems appropriate. All Dissemination Committee decisions must be consistent with the terms of any approvals of the IRB, the Tribal Nation Tribal Government, and the NIH. Dissemination Committee decisions must also be consistent with UW's publication policies, the terms of the grant supporting the project, and usual and customary academic standards pertaining to scholarly publications.

g) *Reporting Requirements*: UW will provide the Tribal Nation HEW Committee with quarterly reports on the progress and status of the Project. Upon completion of the project, UW will provide the Tribal Nation Tribal Council with a community-specific report and an aggregate report that includes findings from the project.

2.2 Ownership of Reports/Publications: The Tribal Nation and UW shall jointly maintain ownership of all Project reviewed and approved reports and publications in which Tribal Nation and UW researchers are co-authors. The Tribal Nation will not retain any ownership interest in reports and/or publications authored solely by UW.

3. DISPUTE RESOLUTION

3.1 Dispute Resolution: Should any disputes arise under this Agreement, the disputing party shall provide the other party with reasonable notice of the dispute. The Parties shall in the first instance resolve the dispute by informal face-to-face negotiations between the Parties' respective technical staff. If unsuccessful, the dispute shall be resolved by face-to-face negotiations at a policy level between UW Administrative Officials and the Tribal Nation Tribal Council in Tribal Council Chambers at the Tribal Nation Agency.

3.2 Termination: Either Party may terminate this agreement for cause by giving thirty (30) days written notice of termination to the other Party. UW shall notify the Tribal Council Chairman atAddress. Notice shall become valid upon receipt by the non-terminating party. Upon termination, all Data shall be returned to the Tribal Nation pursuant to the terms of Section 2 above.

3.3 Sovereign Immunity: Regardless of the terms of this Agreement, the Tribal Nation expressly reserves its sovereign immunity from suit with the execution of this Agreement, and does not waive, alter, or otherwise diminish the rights, privileges, remedies, or services guaranteed to the Tribal Nation by the United States in the Treaty with the Tribals of 1855. 12 Stat. 951. To the extent that this provision conflicts with another provision of this Agreement in any way, this provision shall govern. Should a court of competent jurisdiction determine that this provision cannot be given full legal effect, the entirety of this Agreement shall become null and void.

3.4 Force Majeure: This Agreement is subject to force majeure, and is contingent on strikes, accidents, acts of God, weather conditions, fire, and other circumstances that are beyond the control of the Parties. If the terms and conditions of this Agreement are unable to be performed as a result of any cause of force majeure, then this Agreement shall be void, without penalty to any party for such non-performance.

4. GENERAL TERMS AND PROVISIONS

4.1 Headings. Headings are provided for convenience and do not affect the meaning of the provisions to which they are affixed.

4.2 Severability. If any term of this Agreement is to any extent illegal, otherwise invalid, or incapable of being enforced, such term shall be excluded to the extent of such invalidity or unenforceability; all other terms hereof shall remain in full force and effect; and, to the extent permitted and possible, the invalid or unenforceable term shall be deemed replaced by a term that is valid and enforceable and that comes closest to expressing the intention of such invalid or unenforceable term. Provided, this provision shall have no effect on Section 3.3 herein.

4.3 Entire Agreement. This Agreement (which includes its Exhibits), incorporates all of the agreements, covenants and understandings between the Parties, and supersedes all prior or contemporaneous oral or written agreements between the Parties. No agreement or understanding, verbal or otherwise, of the Parties regarding their responsibilities under this Agreement shall be valid or enforceable unless embodied in the Agreement.

4.4 Amendments. No change, amendment, modification, or addendum to this Agreement shall be valid unless it is in writing and executed by authorized representatives of both Parties.

4.5 Survival. The rights and obligations of Section 2 and Section 3 of this Agreement shall survive termination of this Agreement.

4.6 No General Waiver. Any waiver or failure of the Parties to enforce or insist upon any term in this Agreement does not constitute a general waiver or relinquishment of that term.

4.7 No Construction Against Drafter. Each party has participated in negotiating and drafting this Agreement. If any ambiguity or question of intent or interpretation arises, this Agreement is to be construed as if the Parties had drafted it jointly, as opposed to being construed against one party because it was responsible for drafting one or more provisions.

4.8 Conflicts. In the event of a conflict between the terms and conditions of this Agreement and any other document related to this Agreement, the terms and conditions of this Agreement shall be controlling.

4.9 Execution. This Agreement may be executed in counterparts, electronically, or by facsimile.

University of Washington

By:_____

Print Name:

Title: Director, Office of Sponsored Programs

Date:_____

Tribal Nation

By:_____

Print Name:, Chairman

Title: Tribal Tribal Council

Date:_____

Principal Investigator – Read and Reviewed

By: _____

Print Name:_____

Title:

Date:_____