



Guidelines for Researchers

A Guide to Establishing Effective Mutually Beneficial
Research Partnerships with American Indian Tribes,
Families, and Individuals

March 2023

The Partnership for Native American Cancer Prevention, U54CA143924
Tucson, Arizona

The Partnership for Native American Cancer Prevention (NACP) Outreach Core

The goal of the NACP Outreach Core is to improve the health of American Indian and Alaska Native people by addressing cancer health disparities. The *Guideline for Researchers* is a tool for researchers who work with or are interested in engaging with tribal communities, families, and individuals.

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NACP Outreach Outlets

Facebook



<https://www.facebook.com/nacpoutreach>

NACP Website

For an overview of NACP, please visit:

<https://cancercenter.arizona.edu/researchers/collaborative-research/nacp>



To download the Guidelines for Researchers booklet, please visit:

<https://in.nau.edu/nacp/nacp-outreach-publications-library/>



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Purpose

Within this document are guidelines for researchers on how to conduct respectful and beneficial research in American Indian and Alaska Native (AI/AN) communities. These guidelines cover a variety of topics, including recognizing AI/AN as sovereign nations, how to perform ethical research, understanding AI/AN health disparities, how to navigate the research process, what documentation is needed to perform research, and where to search for additional resources.

The *Guidelines for Researchers* is part of a series that the University of Arizona NACP Outreach has created and are available through our office or at, <https://in.nau.edu/nacp/nacp-outreach-publications-library/>.

Other Guides in the Series include:

How to Build and Sustain a Tribal IRB, Volume I

This document is a guide for American Indian and Alaska Native (AI/AN) tribal communities on:

- How to build a Tribal research review board or an Institutional Review Board
- How to conduct protocol reviews
- How to register a Federal wide Assurance (FWA) or an IRB

How to Review Research to Benefit Tribal Communities, Volume II

This document is a guide for tribal communities on:

- Research in American Indian and Alaska Native Communities
- Questions to Ask during the Research Review Process
- Community-based Participatory Research

How to Conduct Research in American Indian and Alaska Native Communities, Volume III

This document is a guide for researchers on:

- Tribal Sovereignty
- American Indian/Alaska Native Cancer Health Disparities
- Researcher Sensitivity and Responsibility
- Research Checklist

American Indian Cancer Statistics, Volume V

A guide for information on the statistical impact of cancer within American Indian/Alaska populations to:

- Understand cancer statistics by race, region, and sex
- Understand importance of prevention

Tips for Caring for In-Treatment American Indian Cancer Patients, Volume VI

This document is a guide specific to American Indian cancer patient survivors and caregivers on:

- Important communications with health professionals about cancer diagnosis and prescription medication use
- The role of caregivers for cancer patients and how to promote self-care for caregivers

American Indian End of Life Considerations, Volume VII

The document is meant to provide useful information for American Indian caregivers and cancer patients on end of life, including:

- End of life needs specific to physical comfort, mental and emotional needs, spirituality, and practical tasks
- Types of Care: traditional, palliative, and hospice
- Resources to help families get services and support

Clinical Trials, what are they? Volume VIII

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

American Indian/Alaska Native Cancer Survivorship, Volume IX

The purpose of this document is to provide a guide for American Indian/Alaska Native cancer survivors and caregivers on:

- Understanding a survivorship care plan
- Managing life after treatment and continuing to live a healthy life
- Understanding late and long-term effects of cancer treatment

These resources are intended to provide useful and pertinent information to tribes and researchers so that research outcomes can maximize benefit to tribal members and tribal communities. These guidelines are written specifically for research that would involve people, usually called human subjects. Most of the procedures and policies contained within these guides are based on current federal regulations, called *Code of Federal Regulations* (CFR), 45 CFR 46, for *human subjects protection*.

Ultimately, the research being conducted should minimize risks and maximize benefits for AI/AN communities from a cultural/traditional, physical, psychological, spiritual, social, economic, and legal perspective.



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Background

Historically, there have been both domestic and international research initiatives that have caused harm, including death, and which serve as the basis of human subjects protections and regulations that currently exist. In this section, we provide a broad overview of the basis of protections that exist for human subjects: the Nuremburg Code, the Declaration of Helsinki, and the Belmont Report. The next section provides an overview of considerations for conducting research with tribes. In the last section, we provide tools for researchers including checklists.

Research is defined as an investigation designed to develop or contribute to generalizable knowledge.

A *human subject* is described as a living individual from whom an investigator conducting research gathers either data or identifiable private information through the intervention or interaction with the human subject.

The Nuremberg Code

Resulting from the unethical research conducted by the Nazis in Germany and neighboring countries, the Nuremberg Code was established as a direct action from the “Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law” from October 1946 to April 1949. In total, there are ten codes that make up the Nuremberg Code and they are outlined below:

1. The voluntary consent of human subjects is absolutely essential. Human subjects should have the legal right to give consent, to exercise their free power of choice, and to have no intervention of force, fraud, deceit, duress, overreaching, constraint, or coercion to participate in the research project. Human subjects should be given sufficient knowledge and comprehension of the research project so that they make a knowledgeable and enlightened decision.
2. The research experiment should produce positive results for society as a whole that could not be produced by other methods of study. The experiment should not be random and unnecessary.
3. The research experiment should be designed and based on the results obtained from animal experimentation. Combined with knowledge of the natural history of the disease or associated problems, the experiment can be justified based on anticipated results.
4. The research experiment should be conducted in a manner that avoids all unnecessary physical and mental suffering and injury.
5. No research experiment should be conducted when there is a reason to believe that a death or disabling injury will occur; except, perhaps, in experiments where experimental physicians also serve as subjects.
6. The degree of risk of the research experiment should never exceed the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect human subjects from the possibilities of injury, disability, or death.
8. Research experiments should only be conducted by qualified personnel. The highest degree of skill and care are required for all stages of the research project.
9. Human subjects are allowed to stop the experiment at any interval if they believe that their physical or mental abilities have been reached and that continuation of the research project is impossible.
10. Researchers must be prepared to terminate the experiment at any given point if they believe that the continuation of the experiment could result in injury, disability, or death of the human subject.

Declaration of Helsinki

The Declaration of Helsinki states that it is the duty of researchers to promote and safeguard the life, health, privacy, and dignity of human subjects. Above all else, it is the responsibility of researchers to protect the well-being of human subjects over the interests of science and society. Researchers are therefore subjected to practicing ethical standards that promote respect for all human beings and for carefully assessing the need for

research in a given population. Before proposing a research project, the researcher should determine if the potential benefits outweigh the possible risks and burdens.

Special attention is given to vulnerable population that may need additional protection when research projects are introduced into the community. The needs of the economically and medically disadvantaged must be recognized, and only certified scientific researchers can conduct research in any population. All participating human subjects must be volunteer and be fully informed of all procedures and protocols associated with the project. Researchers must also consider if a participant is unable or may refuse to give consent. Special consideration should be considered for human subjects who may be given consent under duress, who will not benefit personally from the research, and for those whom the research is combined with care.

The Belmont Report

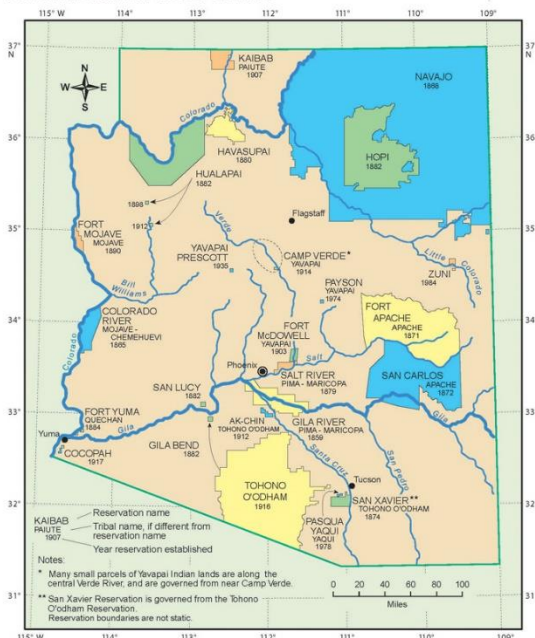
The Belmont Report identifies the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and developing guidelines to assure that such research is conducted in accordance with these principles as a result of the National Research Act of 1974. The three basic principles are *respect for persons*, *beneficence*, and *justice*.

Human subjects should be treated as autonomous agents and subjects with diminished autonomy are entitled to protection. When subjects are presented with sufficient information about the research project, they have to give their informed consent and be given the opportunity to choose what shall or shall not happen to them. Beneficence is an obligation that enforces the concept of not harming the subject, while, maximizing possible benefits and minimizing possible harms. Researchers must enforce justice by providing fair procedures and outcomes in the selection of research subjects.

Research with American Indian and Alaska Native (AI/AN) Tribes

There is a total of 574 federally recognized American Indian/Alaska Native (AI/AN) tribes in the United States and a total of 22 federally recognized tribes in Arizona alone (see Figure 1). Each one of the federally recognized tribes are *Sovereign* nations. With sovereignty comes the establishment of tribal governments, including the ability to protect a tribe's cultures and traditions.

Arizona's Indian Reservations



Research with AI/AN is not the same as working with other underserved, minority, or rural populations.

When working with tribes, researchers need to be familiar with and to be sensitive to culture, traditions, and wishes and/or expectations of a given AI/AN community. Each tribe is unique and needs to be treated as an autonomous entity.

Researchers are encouraged to establish participatory-type relationships with tribes and to have established these relationships prior to proposing research.

For research focused on health, the partners should include the local community health department, and, as applicable the Health Board and/or the Indian Health Service. As the research protocol develops, tribal leadership should be included for review and approval.

No research should begin until there is tribal clearance for the research to begin. The Institution-based review and approval

process is also required. The timing of the processes is situation dependent. It is best to seek guidance from both the tribe and your institution.

In working with tribes, it is important to note that the harms and benefits to be assessed are not necessarily the same as for other populations.

It is imperative to understand the community's

- right to decline participation,
- self-assessment of harms and benefits,
- recognition of community-level harms and benefits,
- (dis)trust of research,
- experience(s) with stereotyping, discrimination, or stigmatization,
- preference for ownership of data,
- request for ways to protect participant and tribal privacy, including how identification occurs in presentations or publications,
- preference for how to handle dissemination and implementation,
- preference for how to handle incidental findings,
- requirement to return results in a timely manner, and
- requirement for transparency, especially related to secondary uses of data.

In Indian Country (the broad reference to all tribes in the U.S.), there has been research done that has harmed AI/ANs. Here we provide two research studies that underscore the importance of respectful research with AI/AN. The first study used data for unapproved secondary uses and the second study that violated tribal community requests for privacy. We also provide approaches that can be implemented to recognize tribal world views and ways to optimize partnerships.

The Diabetes Project with the Havasupai Tribe

In 1989, Arizona State University (ASU) researchers embarked on a research partnership with the Havasupai tribe on a project entitled "*The Diabetes Project with the Havasupai Tribe.*" The objectives of the project were to provide health education, collect and test blood samples, and implement genetic association testing to search for links between genes and diabetes risk for the tribe. Despite years of research, the researchers were not able to find a genetic link to Type II Diabetes among the Havasupai. The researchers then began to change their research project, without the knowledge or consent of the Havasupai tribe, by performing additional studies that were unrelated to the original project. The researchers used collected blood samples to study schizophrenia, migration, and inbreeding. Carletta Tilousi, a Havasupai member and participant of the study, attended a lecture at ASU in March 2003 where she learned that her DNA sample, along with everyone else who participated in the diabetes research project, was being used in non-diabetes-related genetic studies (Garrison, 2012)

Hantavirus Outbreak

In May 1993, an unknown and fatal illness broke out in the Four Corners region of the United States that covers the states of Arizona, New Mexico, Colorado, and Utah (Fred, 1994). The outbreak of hantavirus on the Navajo Nation sparked a national investigation of the illness. Major media outlets that included USA Today, CBC News, the New York Times, and the Arizona Republic titled articles associated with the outbreak as "*Navajo Flu*," "*Navajo Disease*," "*Navajo Epidemic*," and "*In Navajo Land of Mysteries, One Carries a Deadly Illness*" thus promoting an atmosphere of fear focused on the Navajo, stereotyping of the Navajo, invasion of privacy by naming places and identifying the outbreak by a tribe's name, and causing discrimination against the Navajo.

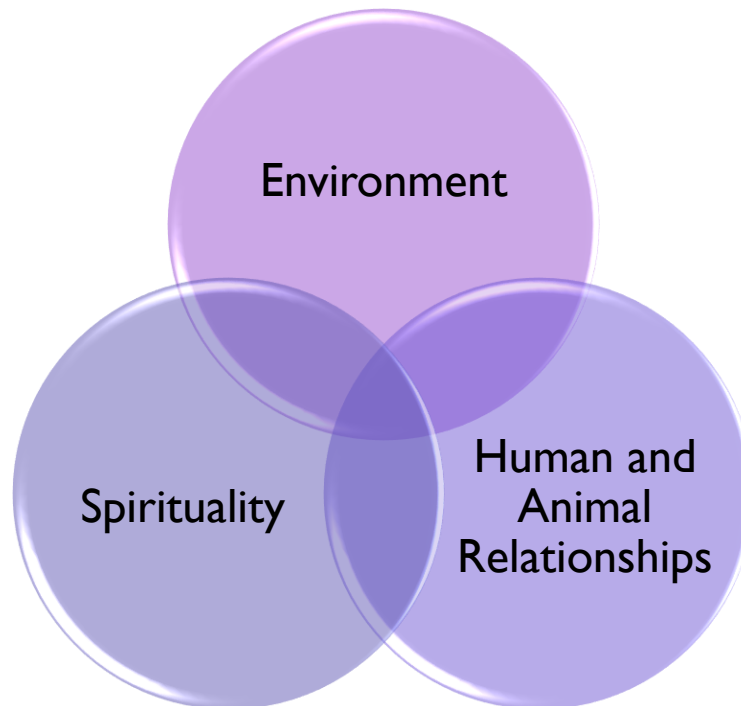
It is important to remember that the purpose of tribal governments is to govern their respective societies. Tribes have the right to approve or disapprove proposed research. Tribes have the right and responsibility to optimize the benefits of the research for the participants and for the tribal community at large.

Traditional Ecological Knowledge

Introduced in the 1980s, Traditional Ecological Knowledge (TEK) is a concept that highlights Indigenous Knowledge (IK) systems and is used to bring about awareness of the existence and value associated with IK (Issac et al., 2018). Knowledge, practices, and beliefs have been handed down for generations regarding the relationships of living beings and the environment creating the concept of TEK (see Figure 2).

AI/AN people have the historical knowledge concerning their own traditional practices and the environment which they have been resided in for thousands of years. In addition, the TEK framework allows the researcher to bridge the gap of perspectives and understandings of the cultural significance of tribal and social practices within the community.

Figure 2. Traditional Ecological Knowledge components



Traditional Ecological Knowledge allows for:

- An approach to local knowledge for physical, mental, and environmental health.
- Connections between tribally based and scientific research.
- Cross-cultural integrations of disciplinary approaches to environmental and health-based knowledge.

Traditional Ecological Knowledge can be incorporated through:

- Language of the AI/AN community.
- Design of the research activities around traditional practices and beliefs.
- Considering community connections, natural resources security, education, cultural use and practices, self-determination, traditional practices, etc.
- Incorporate talking circles and other methods to involve the community voice.

Community-Based Participatory Research (CBPR)

Community-based Participatory Research (CBPR) is a partnership approach to research that equitably involves community members, organizational representatives, and researchers in all aspects of the research process and in which all partners contribute expertise and share decision-making and ownership (Israel et al., 2005). CBPR is an increasingly acceptable approach to tribal communities for establishing research partnerships. Although CBPR exists on a continuum, most partnerships are built on the following fundamental principles:

- Recognize community as a unit of identity.
- Build on strengths and resources of the community.
- Facilitate collaborative partnerships in all phases of the research.
- Integrate knowledge and action for the mutual benefit of all partners.
- Promote a co-learning and empowering process that attends to social inequalities.
- Involve a cyclical and iterative process.
- Address health from both positive and ecological perspectives.
- Disseminate findings and knowledge gained to all partners.

Tribal Participatory Research (TPR)

Tribal Participatory Research (TPR) approaches are viewed as particularly ethical and respectful of research partnerships with sovereign tribal nations (Fisher and Ball, 2003; Thomas et al., 2010). TPR partnerships allow research to be responsive to community needs, to be culturally appropriate, and to be strengths-based while being mindful of the unbalanced and often harmful research previously conducted in tribal communities.



American Indian/Alaska Native Health Disparities

According to the Centers for Disease Control and Prevention (CDC), COVID-19, heart disease and cancer are the top three leading causes of death for AI/AN people (2021) (see Table 1). For cancer, AI/ANs are more likely to be diagnosed with advanced stage cancer compared to Whites (Hoffman et al., 2014) and have higher incidence of kidney cancer, uterine cancer, liver cancer, stomach cancer, gallbladder cancer, and myeloma than Whites (Batai et al., 2018). Related to these, AI/ANs experience varying degrees of issues related to access to health care, such as social structural, physical (transportation and physical distance), supportive, and cultural barriers (Itty et al., 2014). Research to understand the aforementioned is necessary, albeit on AI/AN terms.

Table 1: Top Leading Causes of Death, AI/AN, 2018-2021, Single Race Results
Crude rate per 100,000 population.

Cause of Death	AI/AN Rate 2018-2021
COVID-19	188.6
Heart Disease	153.3
Cancer	129.0
Accidents (Unintentional Injuries)	120.9
Chronic Liver Disease and Cirrhosis	77.4

Conducting Research in AI/AN Tribes – A Checklist

- Get to know the tribal communities and establish relationships.
- Attend meetings and gatherings as a means to develop an appreciation for the history and culture of the tribe.
- Get a clear understanding of the historical trauma experienced by the tribe.
- Demonstrate respect for the community and its indigenous expertise through a Memorandum of Understanding.
- Hire members of the community to serve as consultants on various aspects of the research, such as, data collection.
- A tribe's schedule for tribal ceremonies or tribal rituals should be accommodated.
- Appreciate the Native community's strengths, assets, and challenges.
- Engage the community in the partnership with respect to tribal culture, language, and values.
- Be transparent.
- Undergo tribal and Institutional Review Board (IRB) review and approval.
- Respect the privacy of the tribal community.
- Employ blended research methods that include "indigenous ways of knowing."
- Limit scope of research to focus of questions only.
- Data sources, measures, and collection of information should be fully discussed with the tribe.
- Discuss intellectual and cultural property rights of the information including tribal data ownership.
- Keep the community fully informed as the study progresses and recognize contributions of community members.
- Study findings should be discussed with tribal leadership first.
- Have tribal leaders and key community members review all abstracts, reports, and publications.
- Jointly determine how study results will be presented to the community and public.
- Consider sharing the results of the study in a public community forum.
- Acknowledge and give credit to the community for the scientific results from the study.
- As applicable, consider including key community members as co-authors who participate in writing reports and publications.
- Discuss with the tribal community how they want to be recognized in publications and reports.
- Assist the tribal community in how to address findings of the research.
- Discuss with the tribe the storage and/or destruction of data, especially duration and access.
- Discuss with the tribe any next steps, especially for how data will be stored, for how long, and who has access and responsibility for the project materials and data.

The Review and Approval Steps

The first step to the research process is determining if the AI/AN tribe wants and/or needs the project to be completed within their community, using the recommended approaches. All research involving AI/AN communities must receive the approval of the appropriate tribal governments or organizations. To obtain this approval, researchers should involve all concerned groups as early as possible in the process.

If more than one tribe or tribal organization is involved, a researcher must obtain approval from each entity. If the research project involves academic institutions or the Indian Health Service (IHS), you will need to obtain approval for the project from the academic institutions and IHS as well. Following we provide a brief overview of recommendations for approaching and undergoing tribal, Indian Health Service, and University Institutional Review Board (IRB) review.

The materials that should be submitted include, but are not limited to:

- A cover letter with a list of all the participating researchers and a contact person with a telephone number.
- As applicable, a completed research application.
- As applicable, the Indian Health Service collaborator letter of support.
- As applicable, approval letter from your University IRB.
- A detailed protocol that explains the sampling, recruitment, study design, analyses, timelines, evaluation, reporting, funding, collaborations, and community involvement.
- The informed consent and assent forms.
- Any other attachments, such as copies of flyers, scripts, questions, and/or survey(s) that will be used, materials that will be distributed, etc.

The Tribal Review Process

Any time you are going to engage a tribe in a research project, you must present your idea to them for their review. In many instances, tribes have formed tribal review processes and/or tribal review boards or committees. If these exist, all policies and procedures established by these tribal entities should be followed.

The tribal entities to also be included should be those projects or programs most impacted by the research topic. Similarly, the segment of the population most likely to be recruited for participation should be approached, but only at the introduction by and knowledge of the aforementioned project or program personnel. These individuals, in turn, will serve as the connection to tribal leadership, who have ultimate responsibility to approve or disapprove a project.

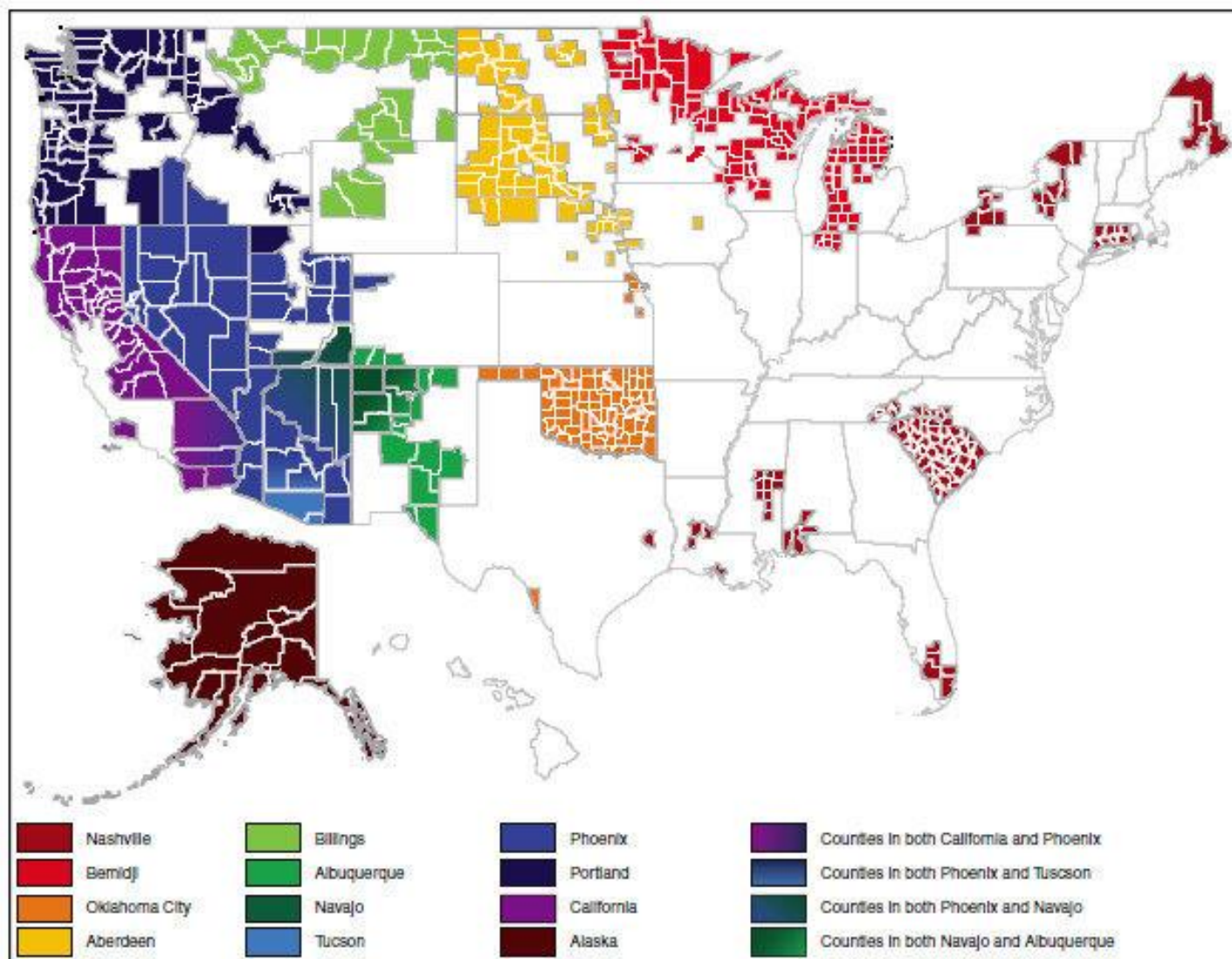
The Indian Health Service (IHS)

The Indian Health Service (IHS) has responsibility to provide health care services to AI/AN people. Through Public Law 93-638 Contracting and Compacting, Indian Trust Self-Governance and Self-Determination, many tribes have taken over their health care delivery system and if this is the case, the aforementioned tribal review process should be undertaken. If the research involves any IHS staff, facilities, data, or program, the IHS review and approval should be sought.

The IHS is hierarchical in structure and the level that is closest to the research project should be engaged (see Figure 3). Within IHS, the IRBs are overseen either directly by IHS personnel or by tribal entities.

In select instances, the Area IRB and the National IHS IRB may request simultaneous review. If there are questions on which IRB review is needed, a researcher should call and seek guidance from any of the IRB Chairs or IRB Coordinators.

Figure 3. Schematic of the Indian Health Service, Service Areas



Source: GAO analysis of IHS information, as of June 2005.

Note: IHS refers to the counties highlighted in this map as contract health service delivery areas. Residence in these counties is generally one of the prerequisites for obtaining contract care services through IHS, while eligibility requirements for direct care services—services provided at an IHS-funded facility—are broader.

Indian Health Service Institutional Review Boards (IRB)

National IRB (NIRB) at IHS Headquarters, Rockville, Maryland: IRB00000646

Rachael Tracy, Chair, IHS National IRB (NIRB)
 Indian Health Service
 5600 Fishers Lane, MS 09E10D
 Rockville, MD 20857
 Phone: 301-443-4700
 Fax: 301-443-0114

Submit projects electronically to irb@ihs.gov with complete hard copy to Rachael Tracy

Alaska Area: IRB00000636

Dr. Shanda Lohse, Chair, Alaska Area IRB
Terry Powell, Administrator, Alaska Area IRB
4315 Diplomacy Drive - RMCC
Anchorage, AK 99508
Phone: 907-729-3924 or 907-729-3917
Email: akaalaskaareaIRB@anthc.org
Submit project electronically to IRBNet.org, Alaska Area IRB

Bemidji Area

Antonio Guimaraes, MD Chair, Bemidji Area Publication Review Committee
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522 Minnesota Avenue, NW
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Phone: 218-335-3200
Fax: 218-444-0498

Billings Area IHS/Rocky Mountain Tribal: IRB00000638

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Fax: 406-254-6355

Great Plains Area: IRB00000635

Dewey Ertz, EdD, Chair, Great Plains Area IRB
Marsha Stevens, GPIRB Coordinator
Phone: 605-226-7493
Fax: 605-226-7214
Toll Free: 866-331-5794

Nashville Area: IRB00000640

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Fax: 615-467-1585

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Phone: 615-467-1628

Navajo Area: IRB00000641

Beverly Becenti-Pigman, Chair, Navajo Nation Human Research Review Board (Navajo Area IHS IRB)
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Office of Planning, Research, Evaluation Program
Navajo Department of Health

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Fax: 928-871-6255



Oklahoma City Area: IRB00000642

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Mobile: 503-927-4467

Tucson Area

Robert Price, Public Health Advisor
Office of Tribal Self-Determination/Tribal Programs (Human participants research clearance is referred to the NIRB)
7900 South J. Stock Road
Tucson, AZ 85746
Phone: 520-295-2403
Fax: 520-295-2540

University-based Institutional Review Board (IRB)

If a researcher is based at a university, institutional review is required if the research includes human subjects. The IRB will have an application and submission process that needs to be followed (see Table 2). All IRB processes and procedures are responsive to the Belmont Report and federal regulations per 45 CFR (Code of Federal Regulations) 46. Most Universities will require researchers to complete human subjects protection training (for example, CITI training – Collaborative Institutional Training Initiative), conflict of interest training, and HIPAA training (Health Insurance Portability and Accountability Act of 1996).

If there are multiple investigators from different universities, one of the Universities can serve as the IRB of record with deferrals from the other IRBs. Tribal IRBs do not usually defer to University IRBs.

Table 2: Institutional Review Boards of Universities known to be conducting research in Arizona

Institution	Contact Information	Website
University of Arizona	(520) 626-7575	https://rgw.arizona.edu/compliance/human-subjects-protection-program
Northern Arizona University	(928) 523-9551	https://nau.edu/nau-research/research-safety-and-compliance/human-research-protection-program/
Arizona State University	(480) 965-6788	https://provost.asu.edu/committees/human-subjects-institutional-review-board
University of New Mexico	(505) 277-2644	https://irb.unm.edu/
New Mexico State University	(575) 646-7177	https://compliance.nmsu.edu/irb/
University of Colorado	(303) 724-1055	https://www.ucdenver.edu/research/comirb/Pages/COMIRB.aspx
Colorado State University	(970) 491-5241	https://www.research.colostate.edu/ricro/irb/
University of Utah	(801) 581-3655	https://irb.utah.edu/
Utah State University	(435) 797-1180	https://rgs.usu.edu/irb/
University of Nevada, Las Vegas	(702) 895-2794	https://www.unlv.edu/research/ORI-HSR
University of Nevada, Reno	(775) 327-2368	https://www.unr.edu/research-integrity/human-research
John Hopkins University	(410) 955-3008	https://www.hopkinsmedicine.org/institutional_review_board/about/

The Universities will also often provide templates from which to complete consent forms and assent forms.

The IRB is assessing *respect for persons*, *beneficence*, and *justice*.

Elements of an IRB Review

1. Understand the research

It is the IRBs responsibility to understand the type and purpose of the research being presented. This is achieved by reading through all of the materials submitted by the researcher. The review board should identify the risks and benefits for both the individual participants and the tribal community. The review board should look at who is included or not included in the research and why. Special attention should be paid to how individuals are being consented and whether the process is sufficient. For example, is a translator or interpreter needed? All information that is being collected should be protected and kept secure. The review board should assess how the tribal community is involved. Are all these adequate and sufficient?

2. Ensure the consent process fully informs and freely consents potential participants

Participants should have the legal capacity to give consent, exercise free power of choice without being tricked or forced to participate, have sufficient knowledge and understanding of the research proposal to make a clear decision.

Voluntary informed consent is an ongoing process, not a piece of paper or discrete moment of time. Researchers should ask for consent only under circumstances that provide the prospective participant or his/her representative sufficient time to consider whether or not to participate in the project.

A researcher should include the following elements when designing a consent form:

- The title of the research study.
- A statement that this is research.
- Reason of eligibility of the subject to participate in the study.
- Approximate number of subjects participating in the study.
- Explanation of the scientific purpose of the study.
- Explanation of the procedures, the time required, and which procedures are experimental.
- Description of reasonably foreseeable risks and discomforts.
- Description of risks to the subject or fetus if the subject becomes pregnant.
- Description of potential benefits to the subject, others, or society in general.
- Description of alternatives to participation.
- Disclosure of costs to the subject and a description of any payment for participating in the study.
- Explanation of available treatment and compensation if subject is injured.
- Information about who to contact with questions regarding the study or subject's rights.
- A statement describing how confidentiality will be maintained.
- A statement describing that participation is voluntary and the subject can withdraw without penalty.
- Circumstances for which a researcher can terminate the subject's participation.
- Disclosure of researcher's financial interest related to the research.
- A consent section for the dated signature of the subject and researcher.
- The name and phone number(s) of researcher(s) and study personnel.

3. Minimize potential harms

Consider potential cultural/traditional, biological, medical, spiritual, psychological, and social harms to the individual, family, and the community, and require steps to ensure potential harms are minimized.

4. Maximize potential benefits

Consider potential cultural/traditional, biological, medical, spiritual, psychological, and social benefits to the individual, family, and the community, and require steps to ensure potential benefits are maximized.

5. Ensure justice

Look at who is being included in the study and assess that all those who could benefit from participation are being included.

6. Obtain additional information

Decide if additional expertise is needed to understand what is being proposed. This may include involving additional experts (researchers, health educators, administrators, etc.) to clarify or provide assistance with the review.

Institutional Review Board Decisions

When an IRB has reviewed a research protocol, they vote and the decision could be to:

- **Approve the Research**-the research can start, and the IRB can request that a researcher provide updates with the time specified, for example, annually.
- **Approve with Recommendations**-the research can start and there are items given to the investigators to make the research project more responsive to local tribal circumstances.
- **Approve with Conditions**-the research cannot start and there are concerns that must be addressed first. The revised research protocol is reviewed once changes have been made.
- **Defer**-the research cannot start, and a decision is not made at all because there are key elements missing. The revised research protocol is reviewed once changes have been made.
- **Disapprove**-the research is disapproved and cannot proceed.



Questions to Ask During the Research Design Process

Significance

- How is the research addressing tribal needs?
- How is the tribe benefitting from the research?
- What are the potential harms? Are they being addressed adequately?

Approach

- How is the information being collected?
- What information is being collected?
- Who is going to be collecting the information?

Data/ Information

- Will personal information be collected?
- How is the information being protected? Who has access to the information?
- How long is the information going to be stored? Where?
- Will the tribe own the data?

Participants

- Who is being included?
- How many individuals are being included?
- Are there children, or others that may need additional considerations being included?

Consent

- Is the consent written in a way that will be easily understood?
- Are translators needed? Is an interpreter needed?
- Are all elements of the project included in the consent form?
- Are individuals being given enough time to make a determination of whether or not to participate?

Questions

- What questions are being asked?
- Are the questions okay to be asked?
- How long will it take to ask the questions?
- If questions are sensitive, is privacy being secured?

Biospecimens

- What is being collected?
- How is the information being protected? Who has access to the information?
- How long is the information going to be stored? Where?
- Will the data be able to be destroyed?

Privacy/ Confidentiality

- How are personal identifiers being handled, for example, name, phone numbers, etc.
- Are participants being told how their information will be protected?
- How is the tribal community being protected?

Referrals

- Are individuals receiving referrals in case there is need for follow-up?
- Are individuals receiving contact lists of someone to call in case they need to talk with someone?
- How are individuals needing follow-up being identified?

Liability

- Who is responsible if something goes wrong?
- Are there conditions under which data might be released? e.g., court order
- What happens if anyone is physically, emotionally, or spiritually hurt?

Capacity Building

- How are tribal community programs being included?
- Are tribal community members being included to help with the research?
- What resources are being allocated to the tribe?

Reporting

- How frequently should the researchers provide updates?
- How will the community be informed of findings?
- Will the tribe review before public dissemination?



Publication

- What are the tribal requests for how abstracts, manuscripts, and reports will identify the tribe?
- Will tribal partners and/or the tribe be co-authors?



Next Steps

- What happens to the information that was collected?
- How long will it be stored? Who has access?
- How will data be destroyed? By whom?

NOTES:

The Research Protocol

The research protocol should provide in detail how the project will be carried out, how the data will be collected and analyzed, and what will be done with the results. Provided below are some points that should be addressed within the research protocol.

Introduction and Background

- Provide relevant research background and explain why this research project is necessary or important.
- Explain why it is necessary to include AI/AN subjects in the research project.
- Explain how the burdens and benefits of the research will be equally distributed.
- Explain if there are other equally suitable groups who could be recruited for this study and why they are not being recruited.
- Describe the potential impact of the proposed research on AI/ANs.
- If a resolution or support letter from the AI/AN tribe has not been obtained, describe how and when it will be. The resolution or support letter should be forwarded to the IRB once it is received.

Study Design

- A complete description of the study design, sequence, and timing of all study procedures that will be performed need to be provided.
- Provide the information for the pilot, screening, intervention, and follow-up phases.
- Include all the materials that will be used in the study, such as surveys, scripts, questionnaires, etc.
- Attach flow sheets if they will help the reader understand the procedures.
- Describe how the study procedures will differ from the standard care that is already available, if it exists.
- If any deception or withholding of complete information is required, explain why this is necessary and attach a debriefing statement.
- Describe where the study will take place.

Participants

- Explain how the nature of the research requires or justifies using human subjects.
- Provide the approximate number and ages for the control and experimental groups.
- Describe the gender and minority representation of the subject population.
- Describe the criteria of selection for each subject group.
- Describe the exclusion criteria for each subject group.
- Describe the source for subjects and attach letters of cooperation from agencies, institutions, or other means of recruitment.
- Explain who will approach the subjects and how they will be approached.
- Explain what steps will be taken to avoid coercion and how to privacy will be protected.
- Submit all advertisement documents, flyers, contact letters, and phone contact protocols.
- Explain if subjects will receive payments, services without charge, or extra course credit.
- Explain if subjects will be charged for any study procedures.

Risk and Benefits

- Describe the nature and amount of risk injury, stress, discomfort, invasion of privacy, and other side effects from all of the study procedures, drugs, and devices.
- Describe the amount of risk the individuals or community may be subjected to.
- Describe how due care will be used to minimize risks and maximize benefits.
- Describe the balance between risks and benefits will be continually reassessed.
- Describe the data and safety monitoring committee, if one exists.
- Describe the expected benefits for individual participants, the community, and society.

Adverse Effects

- Describe how adverse effects will be handled.
- Discuss if the facilities being implemented are adequate to handle possible adverse effects.
- Explain who will be financially responsible for treatment of physical injuries resulting from study procedures.

Confidentiality of Research Data

- Explain if the data will be anonymous with no possible links to identifiers.
- If there are identifiers, explain if they are coded and if the key to the code will be stored separately from the data.
- Explain if any other agency or individual will have access to the identifiable data.
- Explain how the data will be protected.

Consent Forms and Assent Forms

- If the consent form is written, submit copies of all consent and assent forms for each subject group.
- If an oral consent or assent script will be used, submit written scripts for each group.
- If you will not use a consent form or script, submit written justification of waiver of consent per 45 CFR 66.116 (d).

Consent or Assent Processes to Consider

- Would a waiver of consent violate any state or federal statute or customary practice regarding entitlement to privacy or confidentiality?
- Could the research design be modified to eliminate the need for an incomplete disclosure?
- Will the subjects be given more information after completing their participation?
- Is the consent form given and received in a reasonably quiet, unhurried setting?
- Is there a knowledgeable individual present who can answer the questions in a clear manner, using simple terms?
- If children under the age 18 are involved in the study, do you have a parental consent form?
 - If the study involves minimal risk, then the consent of only one parent is needed.
 - If the study involves more than minimal risk, then the consent of both parents is needed.
- If the child is old enough to make some decisions themselves (approximately ages 5-6 years old), is there a form and process that has been set up for their assent?
- Who will explain the research to the potential participants?
- Should someone in addition to or other than the investigator be present?

Drugs, Substance, and Devices

- List all non-investigational drugs or other substances that will be used during the study and include the name, source, dose, and method of administration.
- List all investigational drugs or substances to be used in the study and include the name, source, dose, method of administration, IND number, and phase of testing.
 - INDs must be registered with the appropriate institutional pharmacy. Provide a concise summary of drug information prepared by the researcher, including toxicity data, reports of animal studies, description of studies done in humans, and drug protocol.
- List all investigational devices to be used and provide the name, source, description of purpose, method, and Food and Drug Administration IDE number.
 - If no IDE is available, explain why the device qualifies as a non-significant risk. Attach a copy of the protocol, descriptions of studies in humans and animals, and drawing or photographs of the device.

Research Involving Biospecimens

Many AI/AN have special cultural values and concerns related to the patenting of genes, cloning, and the use of blood and other tissues. Make sure to ask and address the following questions regarding biospecimen collection.

- Does the biospecimen collection and analysis process violate or conflict with cultural values? If so, how will these be addressed? By whom?
- Will the procedures to store biospecimens for use during the project violate or conflict with cultural values? (location and duration of storage of biospecimens)
- Will the procedures to dispose of the collected biospecimens violate or conflict with cultural values?
- Will the biospecimen be stored for future “secondary” studies?
- Are secondary uses of the biospecimen approved by the tribe? What are the terms?
- Is the nature of use adequately described in the research protocol and consent form?
- Make sure to provide signed written agreements to ensure that researchers and others with access to the biospecimen will comply with all procedures to conduct secondary studies.

Additional Information

- Describe the medical, academic, or other personal records that will be used.
- Describe the type of audio-visual recordings, tape recordings, or photographs that will be made.
- Describe if a data safety monitoring board is being included.
- Describe if a Certificate of Confidentiality will be obtained.

Results Interpretation and Dissemination

After the completion of a research project, the collected data and results must be interpreted, analyzed, and reported back to the tribal community in a respectful and understanding manner. Researchers should travel to the tribal communities to present their findings and to discuss with tribal leadership if the research findings should be published or not.

The following are considerations for interpreting and distributing results back to a tribal community.

Interpreting Results

- The information gathered in the study should be relayed to the tribe, research community, and the community, for example, through an open forum.
- The researcher’s interpretation should be shared with the tribe for feedback and input.
- The results should be explained to the program director, tribal health director, health board, and tribal council.
- The information, as applicable, should be stratified by age and sex, and compared with other races, with respect to cell sizes to protect privacy.
- As the results are being written, the tribe should be consulted on findings and narration of tribal identity.
- Results should be relayed through a resilience lens and not a deficit lens.

Reporting and Dissemination

- The tribe needs to approve the final report, manuscript, and dissemination.
- The tribe may require they approve abstracts.
- The tribe should be the first to see and know the results, i.e., before public release.
- Upon approval, the results can then be shared with the tribal community, and then the general public.
- The tribe should be seen as a co-author on publications.
- All peer-reviewed articles should be shared with the tribal community and tribal partners.

Follow-Up (Next) Steps

- Based on the results, the research project should specify additional follow-up or next steps that will be pursued.
- The follow-up or next steps need to be approved by the tribe before continuing.
- All closure understandings should be documented, for example, what happens to collected data, who has access, how long data will be retained, how data will be destroyed, etc.



Resources

For More Information

The University of Arizona Native Peoples Technical Assistance Office provides research support; training and education; and technical assistance for tribal community development at: <https://nptao.arizona.edu/>

The University of Arizona Subjects Protection Program provides information on IRB Assurance and Registration, IRB Roster, Statements of Regulatory Adherence, and fee changes at: <https://rgw.arizona.edu/compliance/human-subjects-protection-program/about-the-irb>

The Northern Arizona University Protocols for Native American Archival Materials contains information about tribal sovereignty and how to conduct respectful research at: <https://www2.nau.edu/libnap-p/protocols.html>

The Northern Arizona University Center for American Indian Resilience has information about community assets, traditional knowledge, and cultural strategies at: <https://in.nau.edu/cair/>

The Arizona State University American Indian Policy Institute supports American Indian tribes for cultural sovereignty, public-policy analysis, and research at: <https://aipi.clas.asu.edu/content/areas-expertise>

The National Congress of American Indians has information about the foundations, ethics, and practices of research resulting in the construction of AI/AN codes, contracts, and IRBs at: <https://www.ncai.org/policy-research-center/initiatives/research-regulation>

The Indian Health Service provides additional resources regarding IRBs, grants, research studies, and programs at: <https://www.ihs.gov/dper/research/researchresources/>

The Office for Human Research Protections issues written guidance's, registers IRBs and FWAs, and provides information about the New Common Rule at: <https://www.hhs.gov/ohrp/>

PRIM&R is a leader for public responsibility in medicine and research providing educational programs and professional development opportunities that can be found at: <https://www.primr.org>

For further information about the Belmont Report, the Nuremberg Code, and Helsinki, please visit the OHRP website at: <https://www.hhs.gov/ohrp/international/ethical-codes-and-research-standards/index.html>

Independent Tribal IRBs

An increasing number of Tribes are forming their own IRBs (below) under 45 CFR 46. Research projects at IHS direct care facilities serving a Tribal Nation that has its own IRB must have the approval of both the Tribal IRB and the IHS IRB. Projects at facilities managed by Tribal Nations with their own IRB and Federal Wide Assurance (FWA) require approval of only the Tribal IRB. Protocols approved by Tribal Research Review Committees that do not meet the formal requirements of 45 CFR 46 for an IRB should also be forward to the IHS IRB for approval. A formal letter of approval from the Tribal Research Committee or IRB is required for consideration by an IHS IRB. This generally takes the place of the Council Resolution or approval letter from an authorized Tribal Health Official that would ordinarily be required. Tribal IRBs that serve a dual role as both a Tribal IRB and an IHS Area Office IRB (Such as the Navajo Nation's IRB) are listed under "IHS IRBs."

American Indian Healing Center, Inc.: IRB00008253 IORG0006887

John Andrews, MPH, Executive Director
12456 E. Washington Blvd.
Whittier, CA 90602
Phone: 562-693-4325
Fax: 562-693-1115

Association of American Indian Physicians: IRB00002261 IORG0001788

Margaret Knight, Executive Director
1225 Sovereign Row, Suite 103
Oklahoma City, OK 73108
Phone: 405-946-7072
Fax: 405-946-7651

Blackfeet Nation: IRB00005802 IORG0004865

Lola Wippert, Chairwoman
Blackfeet Community College
P.O. Box 819
Browning, MT 59417
Phone: 406-338-5421, ext 2252

California Rural Indian Health Board (CRIHB): IRB00004400 IORG0003711

Susan Dahl, MHA, RHIA, CHC, CHP, Chair, CRIHB IRB
4400 Auburn Blvd., 2nd floor
Sacramento, CA 95841
Phone: 916-929-9761 Ext 1400
Fax: 916-929-7246

Cherokee Nation: IRB00001237 IORG0000872

Sohail Kahn, MBBS, MPH, CIP, Co-Chair, Cherokee Nation IRB
Roger Montgomery, MD, Chair, Cherokee Nation IRB
P.O. Box 948
Highway 62
Tahlequah, OK 74465
Phone: 918-453-5602
Fax: 918-431-4148

Chickasaw Nation: IRB00004394 IORG0003705

Sheryl Goodson, Chair, Chickasaw Nation Research Review Committee (RRC)
Carl Albert Indian Health Facility
1001 N. Country Club Road
Ada, OK 74820
Phone: 580-421-4548
Fax: 580-421-6208

Bobby Saunkeah, RN, BSN, CDE, RRC Secretary
Phone: 580-421-4532, Ext. 800
Fax: 580-521-4572

Choctaw Nation: IRB00004293 IORG0003613

David F. Wharton, MPH, RN, Facilitator, Choctaw Nation IRB
Choctaw Nation Health Services
Choctaw Nation Health Clinic - Idabel
902 E Lincoln Road
Idabel, OK 74745
Phone: 580-286-4724
Fax: 580-286-4718

College of Menominee Nation: IRB00007956 IORG0006633

Donna Powless, PhD, Vice-President of Academic Affairs
P.O. Box 1179
N172 State Hwy 47/55
Keshena, WI 54135
Phone: 715-799-5600, Ext. 306
Fax: 715-799-5951

Fond du Lac Band of Lake Superior Chippewa, IRB00012101 IORG0010187

Tonya Kjerland, Research Specialist Human Services Division
927 Trettel Lane
Cloquet, MN 55720
Phone: (218) 655-3623

Haskell Indian Nations University: IRB00003557 IORG0002948

Freda Gipp, Administrative Assistant
155 Indian Avenue
Lawrence, KS 66046
Phone: 785-749-8407
Fax: 785-749-8411

Ho-Chunk Nation IRB

Brenda Owen, IRB Chair
Joan Greendeer-Lee, Secretary
N6520 Lumberjack Guy Road
Black River Falls, WI 54615
Phone: 715-284-9851 ext. 5052

Oglala Sioux Tribal Research Review Board (OSTRRB) (Great Plains)

Katie Blindman, OSTRRB Data Research Assistant
P.O. Box 5011
Pine Ridge, SD 57770
Phone: 605-867-1704
Email: ost.rrb16@gmail.com

Sisseton-Wahpeton Oyate Local Research Review Board (SWOLRRB) (Great Plains)

Heather Larsen, Research Specialist
Local Research Review Board
Education Department
Sisseton-Wahpeton Oyate of the Lake Traverse Reservation
P.O. Box 509 Agency Village, C.P.O.
Sisseton, SD 57262
Phone: 605-698-8411

OR Dr. Sherry Johnson, Education Director

Phone: (605) 698-8298

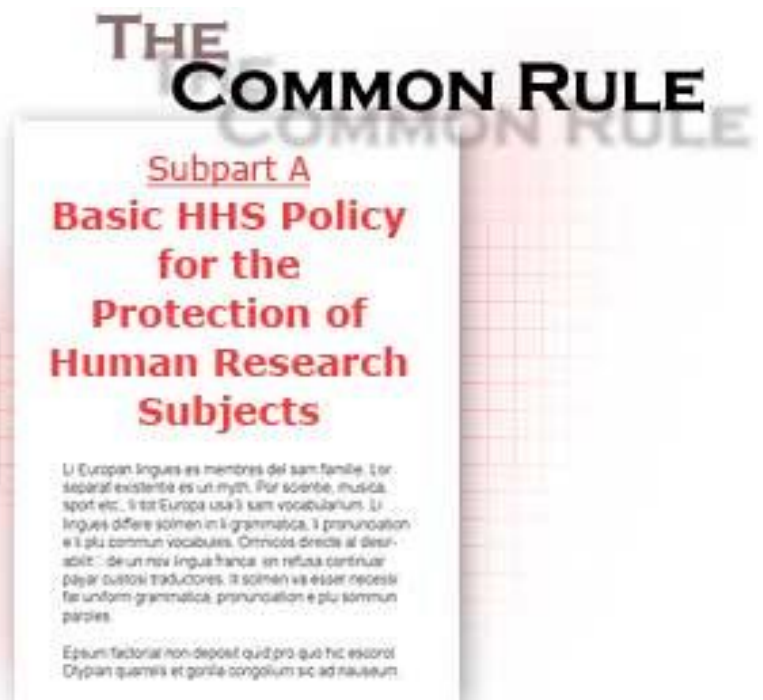
Website: <https://www.swo-nsn.gov/departments/department-of-education/research-office/>

Southwest Tribal IRB (Albuquerque Area)

Marvin Sarracino, Chair
Rachell Tenorio, Coordinator
5015 Prospect Ave NE
Albuquerque, NM 87110
Phone: 505-764-0036
Fax: 505-764-0446 Email: SWTribalIRB@aaihb.org

Tribal Nations Research Group (TNRG) (Great Plains)

Anita Frederick
Tribal Nations Research Group
P.O. Box 1906
Belcourt, ND 58316
Phone: (701) 477-5526
Website: <https://tnrg.org/>



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Appendix

Developing a Protocol

The quality of science is often improved when study objectives and methods are clearly thought through and described. A written protocol facilitates high quality science and is an invaluable tool to investigators as they develop and conduct studies.



Regardless of the scientific discipline in which the study is undertaken, the same scientific method is used. Further, while the scientific content will differ across studies, the general elements of the study protocol will be similar.

The Excellence in Science committee at the Center for Disease Control and Prevention (CDC) has developed a general protocol checklist and companion guide to assist scientists in preparing protocols. The checklist is intended as an aid in suggesting a format for writing protocols and in identifying issues that scientists should consider as they design the study.

The checklist was developed to have utility in conducting laboratory and basic science studies, epidemiologic studies, and behavioral and social science studies employing a variety of study designs. In using checklist, investigators should select the items that apply to their types of studies. It is unlikely that any protocol would include every item on the checklist.

This checklist is intended as an aid in suggesting a format for writing protocols and in identifying issues that scientists should consider as they design a study or surveillance system. When using the checklist, investigators should select the items that apply to their specific project. It is not expected that every item on the checklist is applicable to each protocol for a study or surveillance system.

General Protocol Checklist

Section	Item	√
PROJECT OVERVIEW	Title	
	Protocol summary	
	Investigators & roles/collaborators & roles/funding sources	

PROJECT OVERVIEW

- **Title:** Summarize the main idea under investigation. The title should be able to stand alone as an explanation of the study.
- **Protocol summary:** Give a concise overview of the project. Describe the purpose of the study, including problem to be investigated and hypothesis (es) to be tested, the population, and the methods that will be used. Avoid the use of acronyms. Include the expected benefit of the study.
- **Investigators/collaborators/funding sources:** Include the names and degrees of all investigators and their roles in the project. Note any conflict of interest for each investigator and acknowledge all funding sources.

Section	Item	√
INTRODUCTION	Literature review/current state of knowledge about project topic	
	Justification for study	
	Intended/potential use of study findings	
	Study design/locations	
	Objectives	
	Hypothesis or questions	
	General approach	

INTRODUCTION

- **Literature review/current state of knowledge about project topic:** Discuss relevant information about the subject of the project based on a review of the literature. In the Reference section, attach a bibliography of the sources used.
- **Justification for study:** Explain the public health and scientific importance of the study. In the context of previous studies, describe the contribution this study will make.
- **Intended/potential use of study findings:** Define the primary target audiences and discuss the expected applicability of study findings.
- **Study design/locations:** Describe the study design and the locations where the study will be conducted.
- **Objectives:** Clearly and concisely list the objectives that the project will address.
- **Hypotheses or questions:** List the clear and focused question(s) that the study will answer. State the type of hypothesis(es) that will be explored or tested.
- **General approach:** Describe whether the approach used will be descriptive, exploratory (hypothesis-generating), confirmatory (hypothesis testing), or developmental (focused on corrective action).

Section	Item	√
PROCEDURES/METHODS DESIGN	How study design or surveillance system addresses hypothesis and meets objectives	
	Audience and stakeholder participation	
	Study time line	

PROCEDURES/METHODS - DESIGN

- **How study design or surveillance system addresses hypotheses and meets objectives:** Explain the appropriateness of the study design to the project and to the question and objectives previously outlined. Distinguish between procedures that are experimental and those that involve routine care. Identify specific design attributes that characterize the study design (e.g., description of the system as active or passive, defining reported cases as individuals versus aggregate and as laboratory confirmed or not).

- **Audience and stakeholder participation:** Define the primary audiences for the project. Assess the major stakeholders and describe ways they can (and cannot) participate in the study. Explain the process by which those affected by the study can express their views, clarify their needs, and contribute to the project.
- **Study timeline:** Provide a calendar with estimated dates for implementing and completing key activities.

Section	Item	√
PROCEDURES /METHODS STUDY POPULATION	Description and source of study population and catchment area	
	Case definitions	
	Participants inclusion criteria	
	Participants exclusion criteria	
	Justification of exclusion of any sub-segment of the population	
	Estimated number of participants	
	Sampling, including sample size and statistical power	
	Enrollment	
	Consent process	

PROCEDURES/METHODS - STUDY POPULATION

- **Description and source of study population and catchment area:** Demographically and in terms of the specific public health conditions to be studied, defined the population from which the participants, sample, or surveillance subjects will be drawn and to what population inferences will be made.
- **Case definitions:** Provide descriptions of illness, condition or health event which defines a study participant as having that condition.
- **Participant inclusion criteria:** Describe conditions or characteristics applicable to the identification and selection of participants in the study and the conditions necessary for eligible persons to be included.
- **Participant exclusion criteria:** Describe characteristics that would disqualify otherwise eligible participants from the project.
- **Justification of exclusion of any sub-segment of the population:** If a sub-population as define by gender, race/ethnicity, or age is excluded, provide reasons.
- **Estimated number of participants:** State the estimated number of participants for the study. For a project established or using data from a surveillance system, this may include the expected number of reported cases per reportig period for epidemic and non-epidemic periods.
- **Sampling, including sample size and statistical power:** Describe the sample (e.g., the sample will be one of convenience, a population-based representation or systematically chosen for some other purpose). State the sampling units and units of analysis. Estimate required sample sizes to answer questions and test statistical hypotheses (based on available information from pilot studies or previous reports). Include statistical power estimates. Explain the conditions under which sampling estimates would be revised. If group-level or aggregated information will be collected (e.g., from focus groups), explain how the groups will be comprised, or what procedures will be followed to create appropriate groups.

- **Enrollment:** Describe the manner in which potential participants will be contacted, screened, and registered in the study. Describe procedures for tracking the number of persons who withdraw from the study. Explain the procedures for assigning participants to different groups. Include a discussion of how departures from the intended enrollment procedures will be handled and documented.

Section	Item	√
PROCEDURES/METHODS VARIABLES/INTERVENTIONS	Variables	
	Study instruments, including questionnaires, laboratory instruments and analytic test (including abstract form, paper and electronic)	
	Training for all study personnel	

PROCEDURES/METHODS - VARIABLES/INTERVENTION

- **Variables:** List and briefly describe the categories, topics, or domains of information to be explored and variables to be collected. Address consistency of definition of variables for data collected from multiple sources. Traditionally, for outbreak investigations, “time,” “place,” and “person” would be collected to construct the epidemiologic curve. Explain how the variables will be utilized and the process by which variables will be defined.
- **Study instruments, including questionnaires, laboratory instruments, and analytic tests:** Describe strategies to elicit information, including specific techniques and study and laboratory instruments, and explain how they will be used. Describe the attributes of those strategies/instruments as demonstrated in other studies, including appropriateness, validity and reliability within the particular study populations, sensitivity and specificity of instruments, how well they yield reproducible results and whether any controversial methods are being used. Include a discussion of how changes to the study instruments will be handled and documents.
- **Training for all study personnel:** Describe training, such as interviewer techniques, data collection and handling methods or informed consent, provided to study personnel. Address how inter-observer differences will be handled.

Section	Item	√
PROCEDURES/METHODS DATA HANDLING AND ANALYSIS	Data analysis plan, including statistical methodology and planned tables and figures	
	Data collection	
	Data entry, editing and management, including handling data collection forms, different versions of data and data storage and disposition (including treatment data consolidation)	
	Quality control/assurance	
	Bias in data collection, measurement and analysis	
	Intermediate reviews and analyses (pilot test)	
	Limitations of study	

DATA HANDING AND ANALYSIS

- **Data analysis plan, including statistical methodology and planned tables and figures:** Describe the sampling methods, information collection procedures, methods to maximize response rates, test procedures and relevant statistical quantities (e.g., variance, confidence intervals and power based on data from the study) in sufficient detail that the methods are reproducible. This includes calculation of relevant quantitative measures for methods and reproducible. This includes calculation of relevant quantitative measures for test and instruments, such as sensitivity and specificity. In outbreak investigations, it is common to employ an iterative process in the analysis (consisting of developing and testing hypotheses and planning and evaluating interventions) to identify the source of the outbreak and control it. For projects establishing or utilizing data from a surveillance system, this could include how and how often the surveillance system will be evaluated. Describe what tables and figures are planned to present study results.
- **Data collection:** Describe data collection procedures, processes and documentation. For data emanating from a surveillance system, this would include frequency or reports.
- **Information management and analysis software:** Provide the names of data entry, management and analysis software packages and computer programming languages to be used for the project.
- **Data entry editing and management, including handling of data collection forms, different versions of data, and data storage and disposition:** Describe the overall procedures for management of the data collected. Include in the description the process for entering and editing data. Describe how study materials, including questionnaires, statistical analyses, unique reagents, annotated notebooks, computer programs and other computerized information, whether used for publication or not, will be maintained to allow ready, future access for analysis and review. Document operating procedures for managing and accessing different versions of data sets. State who the data belong to and any rights to and limitations to access for any primary and secondary data analyses and publications. Document procedures regarding confidentiality of the data, including how confidentiality will be preserved during transmission, use and storage of the data and the names of persons or positions responsible for technical and administrative stewardship responsibilities. Document what the final disposition of records, data, computer files, and specimens will be, including location for any relevant information to be stored.
- **Quality control/assurance:** Describe the steps that will ensure no unintended consequences that could affect the quality of the data. Those steps might include methods to capture all reported data exactly as received, assuring logical consistency among all parts of a record and ensuring that manipulation or transformation of the data (e.g., from audio tape to transcribe text) produces no unintended changes, and verifying that statistical and arithmetic calculations are performed as proposed in the data analysis plan. For outbreak investigations, this would include verifying diagnosis and confirming the outbreak. Describe procedures for ongoing data quality monitoring to assure that information of appropriate depth, breadth, specificity is collected and remains consistent within and among staff over time, and acceptable levels of such attributes as validity, reliability, reproducibility, sensitivity and specificity are achieved.
- **Bias in data collection, measurement and analysis:** Describe the kinds of bias that may occur in collecting the data or in the measurement or analysis phases, and the steps that will be taken to avoid, minimize and compensate for the bias. Include factors in the study population or in study personnel that could bias results, as well as the steps that will be taken to assure valid self-reporting or recording of observations. Include any randomization and blinding procedures that will be used to eliminate/minimize bias by investigators, other study staff or participants (e.g., in selection of participants, allocation to treatment groups, providing/receiving treatment).

- **Intermediate reviews and analyses:** Describe the ways that progress will be tracked and the study will be evaluated prior to assessing final results.
- **Limitations of study:** Explain factors that might reduce the applicability of study results. Discuss potential weak points or criticisms of the study, including alternative methods.

Section	Item	✓
PROCEDURES/METHODS DISSEMINATION, NOTIFICATION, AND REPORTING OF RESULTS	Notifying participants of study findings	
	Anticipated products or inventions resulting from the study and their use	
	Disseminating results to public (including data publication guidelines and manuscript writing roles)	
REFERENCES	Literature searches	
APPENDIX MATERIALS	Data collection forms	
	Proposed tables and figures	
	Other relevant documents	

