Guidelines for Researchers

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

March 2019

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

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Purpose

This document is a guideline 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 online on our website, www.uacc.nacp.outreach.

The other guides in the series includes:

**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; and,
- How to register a Federalwide 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; and,
- Community-based Participatory Research

**How to Conduct Research, Volume III**

This document is a guide for researchers on:

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

These resources are intended to provide useful and pertinent information to tribes and researchers so that outcomes can benefit 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 Nuremberg 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 and sample documents.

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 disadvantage 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 are a total of 573 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.

![Research with AI/AN is not the same as working with other underserved, minority or rural populations.](image)

When working with tribes, researchers need to 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. Usually, the Institution-based review and approval process is also required. The timing of the processes are 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, which is an inherent right to self-government. Tribes are sovereign nations. 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 Cancer Health Disparities

According to the Indian Health Service (IHS), heart disease and cancer are the top two leading causes of death for AI/AN people (2018) (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 and US All Races Rates.

<table>
<thead>
<tr>
<th>Cause/Disease</th>
<th>AI/AN Rate 2009-2011</th>
<th>US All Races Rate 2010</th>
<th>AI/AN to U.S. All Races</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Disease</td>
<td>194.7</td>
<td>179.1</td>
<td>1.1</td>
</tr>
<tr>
<td>Cancer</td>
<td>178.4</td>
<td>172.8</td>
<td>1.0</td>
</tr>
<tr>
<td>Accidents</td>
<td>93.7</td>
<td>38.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Diabetes</td>
<td>66.0</td>
<td>20.8</td>
<td>3.2</td>
</tr>
<tr>
<td>Respiratory Diseases</td>
<td>46.6</td>
<td>42.2</td>
<td>1.1</td>
</tr>
</tbody>
</table>
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 open 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 aforementioned 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. In the Appendix, we provide some sample documents to use as reference.

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. The National IHS IRB (oversees research in Bemidji Area and Tucson Area) and Oklahoma Area are overseen by IHS. The other Area IRBs are overseen by tribal entities such as the tribal consortia in that Area. In the latter instance, research occurring on tribal lands within that region may be included within the purview of research review.
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, see following:

**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
(Human participants research clearance is referred to the NIRB)
522 Minnesota Avenue, NW
Bemidji, MN 56601
Phone: 218-335-3200
Fax: 218-444-0498

Billings Area IHS/Rocky Mountain Tribal: IRB00000638
Vernon Grant, PhD, Chair
Karen Manzo, PhD, MPH, IRB Coordinator
711 Central Ave, Suite 220
Billings, Montana 59102
Phone: 406-252-2550; 406-697-2436 (c)
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
John Shutze, MPH, Chair, Nashville Area IHS IRB
711 Stewarts Ferry Pike
Nashville, TN 37214
Phone: 615-467-1669
Fax: 615-467-1585

Navajo Area: IRB00000641
Beverly Becenti-Pigman, Chair, Navajo Nation Human Research Review Board (Navajo Area IHS IRB)
Michael Winney, Administrative Assistant
Office of Planning, Research, Evaluation Program
Navajo Department of Health
P.O. Box 1390
Window Rock, Arizona 86515
Phone: 928-871-6929/871-6352
Fax: 928-871-6255
Oklahoma City Area: IRB00000642

Greggory Woitte, MD, FACOG
Ryan Schupbach, PharmD, BCPS, CACP
CAPT, U.S. Public Health Service
Co-Chairman, Institutional Review Board
Indian Health Service, Oklahoma City Area
701 Market Drive, Oklahoma City, OK 73114
Phone: (405) 951-3928

Phoenix Area: IRB00000643

Cynthia Claus, PhD, MPH, Chair, Phoenix Area IHS IRB
Two Renaissance Square
40 North Central Avenue Suite 600
Phoenix, AZ 85004
Phone: 602-364-5169

Portland Area: IRB00000645

Rena Macy, Co-Chair, Portland Area IHS IRB
Portland Area IHS
1414 NW Northrup St Suite 800
Portland, OR 97209
Phone: 503-414- 5540

CAPT Thomas Weiser, MD, MPH, Co-Chair
Portland Area IHS IRB, Northwest Portland Area Indian Health Board
2121 SW Broadway #300, Portland OR 97201
Phone: 503-416-3298
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

<table>
<thead>
<tr>
<th>Institution</th>
<th>Contact Information</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Arizona</td>
<td>(520) 626-7575</td>
<td><a href="https://rgw.arizona.edu/compliance/human-subjects-protection-program">https://rgw.arizona.edu/compliance/human-subjects-protection-program</a></td>
</tr>
<tr>
<td>Northern Arizona University</td>
<td>(928) 523-9428</td>
<td><a href="https://nau.edu/nau-research/research-safety-and-compliance/human-research-protection-program/">https://nau.edu/nau-research/research-safety-and-compliance/human-research-protection-program/</a></td>
</tr>
<tr>
<td>Arizona State University</td>
<td>(480) 965-6788</td>
<td><a href="https://provost.asu.edu/committees/human-subjects-institutional-review-board">https://provost.asu.edu/committees/human-subjects-institutional-review-board</a></td>
</tr>
<tr>
<td>University of New Mexico</td>
<td>(505) 277-0472</td>
<td><a href="https://irb.unm.edu/">https://irb.unm.edu/</a></td>
</tr>
<tr>
<td>New Mexico State University</td>
<td>(575) 646-7177</td>
<td><a href="https://compliance.nmsu.edu/irb/">https://compliance.nmsu.edu/irb/</a></td>
</tr>
<tr>
<td>University of Colorado</td>
<td>(303) 724-1058</td>
<td><a href="https://www.ucdenver.edu/research/comirb/Pages/COMIRB.aspx">https://www.ucdenver.edu/research/comirb/Pages/COMIRB.aspx</a></td>
</tr>
<tr>
<td>Colorado State University</td>
<td>(970) 491-5727</td>
<td><a href="https://www.research.colostate.edu/ricro/irb/">https://www.research.colostate.edu/ricro/irb/</a></td>
</tr>
<tr>
<td>University of Utah</td>
<td>(385) 419-0712</td>
<td><a href="https://irb.utah.edu/">https://irb.utah.edu/</a></td>
</tr>
<tr>
<td>Utah State University</td>
<td>(435) 797-0567</td>
<td><a href="https://rgs.usu.edu/irb/">https://rgs.usu.edu/irb/</a></td>
</tr>
<tr>
<td>University of Nevada, Las Vegas</td>
<td>(702) 895-2794</td>
<td><a href="https://www.unlv.edu/research/ORI-HSR">https://www.unlv.edu/research/ORI-HSR</a></td>
</tr>
<tr>
<td>University of Nevada, Reno</td>
<td>(775) 327-2367</td>
<td><a href="https://www.unr.edu/research-integrity/human-research">https://www.unr.edu/research-integrity/human-research</a></td>
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<tr>
<td>John Hopkins University</td>
<td>(410) 955-3008</td>
<td><a href="https://www.hopkinsmedicine.org/institutional_review_board/about/">https://www.hopkinsmedicine.org/institutional_review_board/about/</a></td>
</tr>
</tbody>
</table>

The Universities will also often provide templates from which to complete consent forms and assent forms, for example. In these Guidelines we provide forms from the University of Arizona as sample documents. 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, which, may be advantages to the subject.
- 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?
NOTES:

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?
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 general public, for example, through a community 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/](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](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](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/](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](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](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/](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/](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](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](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

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

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
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: SISSETON WAHPETON OYATE OF THE LAKE TRAVERSE RESERVATION RESEARCH OFFICE

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: Tribal Nations Research Group
References


Native American Center for Excellence, Substance Abuse Prevention, Steps for Conducting Research and Evaluation in Native Communities. Available at: https://www.samhsa.gov/sites/default/files/nace-steps-conducting-research-evaluation-native-communities.pdf


Appendix

- Developing a Protocol
- Northern Arizona University Determination of Human Research 2018-08
- University of Arizona Application for Human Research
- Northern Arizona University Amendment of Approved Human Research v2018-08
- Northern Arizona University Continuing Review v2018-08
- Northern Arizona University Non-Federally funded consent form vJan2019
- Northern Arizona University Federally funded consent form vJan2019
- Northern Arizona University Biomedical consent form vJan2019
- Northern Arizona University Biomedical consent form HIPAA Auth Combined vJan2019
- Northern Arizona University Parental Permission form vJan2019
- Northern Arizona University Minor assent-young aged <8 vJan2019
- Northern Arizona University Minor assent-middle aged 9-15 vJan2019
- Northern Arizona University Consent Online Survey vJan2019
**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**

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<td>PROJECT OVERVIEW</td>
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<td>Protocol summary</td>
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<td>Investigators &amp; roles/collaborators &amp; roles/funding sources</td>
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**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.
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).

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.

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

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<tr>
<th>Section</th>
<th>Item</th>
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<tbody>
<tr>
<td>PROCEDURES/METHODS VARIABLES/INTERVENTIONS</td>
<td>Variables</td>
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<td></td>
<td>Study instruments, including questionnaires, laboratory instruments and analytic test (including abstract form, paper and electronic)</td>
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<td>Training for all study personnel</td>
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</table>

**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 documented.

• **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.

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

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<th>Section</th>
<th>Item</th>
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<tbody>
<tr>
<td>PROCEDURES/METHODS DISSEMINATION, NOTIFICATION, AND REPORTING OF RESULTS</td>
<td>Notifying participants of study findings</td>
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<td>Anticipated products or inventions resulting from the study and their use</td>
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<tr>
<td></td>
<td>Disseminating results to public (including data publication guidelines and manuscript writing roles)</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>Literature searches</td>
</tr>
<tr>
<td>APPENDIX MATERIALS</td>
<td>Data collection forms</td>
</tr>
<tr>
<td></td>
<td>Proposed tables and figures</td>
</tr>
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<td></td>
<td>Other relevant documents</td>
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</table>
This form should be used when it is unclear whether the proposed activities require review by an Institutional Review Board (IRB). If the proposed study clearly is Human Research, do not complete this form! Instead, please submit the appropriate application for review and approval by the IRB.

The Human Research Subjects Protection Program (HRPP) will provide a written determination. This determination can be used to provide sponsors, collaborators, and journal editors who want verification from an impartial source that the activities do not require IRB approval. To have a successful determination, complete the entire form and submit it to the IRB office through IRBNet.

Section 1: Contact Information

Project Title (If funded, provide exact title of funded project)

Principal Investigator Name, Degree(s):

Status/Rank:

Department:

College:

Contact phone:

Official Institutional Email:

Faculty Advisor Name, Degree(s):

Department:

Contact phone:

Official Institutional Email:

Section 2: General Information

1. Project funding - If the proposed study is or will be funded, complete below:
   a. Funding PI:
   b. Proposal Title:
   c. Funder Name:
   d. Total funding amount OR per subject amount:

2. Location of Research:

Section 3: Summary of Activities
1. Provide a concise description of the purpose or objectives of the project.

2. Describe the proposed methods and study procedures

3. Describe how data collection will occur, where the study will take place, and the type of information to be collected? If applicable, include a list of the data elements to be abstracted or collected.

4. If applicable, describe the maximum number of subjects needed to complete the project. If it involves more than one activity or more than one population, each must be identified. (i.e. The interview phase will include 50 students. The survey will be administered to 500 students.)

Section 4: Research per OHRP

45 CFR 46.102(l): Research - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A systematic approach involves a predetermined system, method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach includes the collection of information and/ or biospecimens, and analysis either quantitative or qualitative.

Activities designed to develop or contribute to generalizable knowledge are those activities designed to draw general conclusions, inform policy, or generalize outcomes beyond the specific group, entity, or institution (i.e., to elaborate, to be an important factor in identifying or expanding truths, facts, information that are universally applicable).

<table>
<thead>
<tr>
<th>Does the proposed activity involve a systematic approach?</th>
<th>☐ *Yes ☐ No</th>
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<tr>
<td>Is the intent of the proposed activity to develop or contribute to generalizable knowledge?</td>
<td>☐ *Yes ☐ No</td>
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</table>

*If Yes to BOTH questions the study is Research. Proceed to Section 5.

If the answers to one or both questions are NO, proceed to Section 6 to determine if the activity is subject to the Food and Drug Administration (FDA) regulations.

Section 5: Involvement of Human Subjects per OHRP
Determination of Human Research

**45 CFR 46.102(e):** Human subject - a living individual about whom an investigator (whether faculty, student, or staff) conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

*Intervention* includes both physical procedures by which information is gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

*Interaction* includes communication or interpersonal contact between investigator and subject.

*Private* information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record information). Private information must be individually identifiable.

*Identifiable* is where the identity of the subject is or may be ascertained by the researcher, or will be associated with the information. The research could involve the use of coded data/specimens.

Does the activity involve obtaining information about living individuals through intervention or interaction with the individuals? *Yes  No*

Does the activity involve obtaining identifiable and private information about living individuals? *Yes  No*

*If YES to either question, the research activity is research that involves human subjects. STOP and submit an IRB application for approval of human research.*

If the answers to one or both questions are NO, proceed to Section 6 to determine if the activity is subject to the Food and Drug Administration (FDA) regulations.

**Section 6: Clinical investigation per FDA**

**21 CFR 50.3(g):** Human subject - an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

*Test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation.

**In vitro diagnostic** products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae.

This is a clinical investigation involving a test article including in vitro diagnostics with a human subject(s) or their biospecimens? *Yes  No*
**Determination of Human Research**

* If NO, proceed to section 7. If YES, complete all Section 6.

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<tbody>
<tr>
<td>a. An individual will be a recipient of any test article* (i.e. drug, biologic, or medical device) or as a control.</td>
<td>☐ *Yes ☐ No</td>
</tr>
<tr>
<td>b. An individual on whose specimen a medical device will be used (21 CFR 812.3(p)) (i.e. In vitro diagnostic** device).</td>
<td>☐ *Yes ☐ No</td>
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</table>

**Note:** The FDA regulations (21 CFR Parts 50 and 56) apply to all clinical investigations regulated by FDA, as well as other clinical investigations that support applications for research or marketing permits. Therefore, all studies of investigational IVDs that will support applications to FDA are subject to 21 CFR Parts 50 and 56, even if they are not subject to most requirements of 21 CFR Part 812. For more information see the FDA Guidance on In Vitro Diagnostic Device Studies - FAQs.

*If YES to ANY question, the activity is subject to the FDA regulations. STOP and submit an IRB application for approval of human research.

If ALL answers are NO, proceed to Section 7.

**Section 7: Coded private information and/or human biological specimens per OHRP**

* Coded means identifiable information, such as name or social security number has been replaced by a code (i.e. a number, letter, or combination thereof) AND there is a key to link between the code and the identifiable information.

Does the study involve use of coded data/specimens?  
* If NO, proceed to section 8. If YES, complete Section 7.  

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<td>Yes ☐ * No</td>
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Please explain what data/specimens consists of (if it includes PHI elements please list them):

The data/specimens were collected for the proposed project?  
* If NO, STOP and submit an IRB application for approval of human research.  

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<td>Yes ☐ * No</td>
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The provider of the data/specimens will remove the code before sending the data/specimens to the researcher?  
*If NO, STOP and submit an IRB application for approval of human research.  
*If any answer is YES, complete the section below. Identify the method for removing the code below.

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The holder of the key and researcher enter into an agreement prohibiting the release of the key to the researcher under any circumstances?

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The researcher has documented written policies and procedures from a repository or data management center that prohibits the release of the key to the researcher under any circumstances?

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<td>*Yes ☐ No</td>
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There are other legal requirements prohibiting the release of the key to the researcher?

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<td>*Yes ☐ No</td>
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*STOP! For HRPP determination, submit copies of the informed consent from the study where the data/samples were collected, agreements, or policies and procedures preventing access to the code for review.  
*If NO to all questions, STOP and submit an IRB application for approval of human research.
Section 8: De-identified private information or specimens

De-identified means the complete removal of all identifiers, (e.g. HIPAA identifiers – see appendix), and that the information or combination thereof cannot be combined to identify an individual or readily ascertained by the investigator.

NOTE: Analysis of video, image, or digital recordings is considered identifiable.

The investigator will only receive information/specimens that are fully de-identified? (meaning, the investigator will not collect or remove the identifiers themselves.)

*Yes  No

Explain where the information/specimens were collected/obtained (i.e. identify source of data/specimens):

Proceed to Section 9.

Section 9: Non-Human Research Activities

Many proposed activities may involve people or their data, but may not be human research. The University of Arizona has determined the following activities to NOT represent Human Subjects Research.

NOTE: Investigators may have obligations under HIPAA (as noted below).

☐ Case Report: The proposed activity is a case report or case series of no more than three (3) cases describing an interesting treatment, presentation, or outcomes?
  • If case report requires PHI, a researcher outside of the Covered Entity must obtain a signed HIPAA Authorization from the subject/patient.
  • If you intend to disclose PHI as part of any case report, you must obtain a signed HIPAA Authorization from the subject/patient.

☐ Program Evaluation/Quality Improvement/Quality Assurance: The proposed activity will assess, analyze, critique, and improve current processes of program or health care delivery in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements in a program or health care delivery?
  • The activity will NOT involve randomization to different intervention groups.
  • The activity WILL improve clinical care.
  • The activity will NOT be applied to populations beyond the specific study population (e.g. the knowledge gained from the activity is unique to the Northern Arizona University).
  • The activity will not affect clinical decision making for an individual patient vs. a population of patients.

NOTE: Researchers outside of the Covered Entity may not conduct PE/QI/QA unless specifically authorized by the Covered Entity and pursuant to a Business Associate Agreement. Please contact the HIPAA Privacy Officer at Beth.Applebee@nau.edu or (928) 523-6347 for additional information.
Course-Related Activities: The proposed activity is limited to course-related activities designed specifically for educational or teaching purposes?
- The activity is part of a routine class exercise or assignment for a grade.
- The activity is meant to teach research or professional methodology.

Oral History: The activity is limited to oral history activities, such as open ended interviews that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings.

Public Use Datasets: The activity is limited to analyzing de-identified data contained within a publically available dataset. **NOTE:** This does not include reviewing or analyzing information from social media.
- Restricted use data sets do not qualify.

Journalism/Documentary Activities: The activities are limited to investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis?
- IRB approval may be required when journalists conduct activities normally considered scientific research intended to produce generalizable knowledge.

Purchased cell lines: The activity involves commercially available, de-identified non-human embryonic cell lines.

Database creation: The primary reason for establishing this database is for clinical purposes or an improvement project (IRB approval of a new protocol must be obtained before any data from this database may be used for research purposes).

**NOTE:** For some records and database research, a signed HIPAA Authorization may not be needed.

dbGap: Receipt of data from dbGap that requires IRB approval, but the data you will receive:
- Is de-identified, but the Data Use Committee requires IRB approval
- The researcher did not submit any of the original data to dbGap
- The researcher will not collaborate with others on the project who submitted the original data to dbGap

Investigators must also submit an Institutional Certification form to be completed and signed by the Investigator and IRB.

Limited Data Set- A limited data set is PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (i) names; (ii) postal address information, other than town or city, state, and ZIP code; (iii) telephone numbers; (iv) fax numbers; (v) e-mail addresses; (vi) Social Security Numbers; (vii) medical record numbers; (viii) health plan beneficiary numbers; (ix) account numbers; (x) certificate/license numbers; (xi) vehicle identifiers and serial numbers, including license plate numbers; (xii) device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv) biometric identifiers, including finger and voice prints; and (xvi) full face photographic images and any comparable images.

**NOTE:** Researchers outside of the Covered Entity may not have access to medical records unless specifically authorized by the Covered Entity and pursuant to a Business Associate Agreement. Please contact the HIPAA Privacy Officer at Beth.Applebee@nau.edu or (928) 523-6347 for additional information.
### Preparatory to Research
Are you reviewing PHI preparatory to research?

- The information is necessary and is used solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research.
- No PHI is to be removed from the covered entity by the researcher in the course of the review.

**NOTE:** Researchers outside of the Covered Entity may not access to medical records unless specifically authorized by the Covered Entity and pursuant to a Business Associate Agreement. Please contact the HIPAA Privacy Officer at Beth.Applebee@nau.edu or (928) 523-6347 for additional information.

### PHI of Decedents
The activity is necessary and is limited to death records, autopsy materials, or cadaver specimens?

- Note: Access to psychotherapy notes or information related to HIV, mental health, genetic testing, or drug or alcohol abuse may not be applicable.
- Note: PHI does not include information regarding a person who has been deceased for more than 50 years.

### Native American/Alaskan Native
The activity involves access to tribal resources (e.g. cultural artifacts, environmental samples, or people), but the activity is not intended to produce generalizable knowledge. See NAU Tribal Consultation Policy.
Application for Human Research

Title (If funded, provide exact title of funded project)

Contact information
Principal Investigator Name
Net ID
UA Email Address
College/Division
Department/Unit
Status
☐ Undergraduate Student  ☐ Graduate Student  ☐ Resident  ☐ Faculty  ☐ Staff

Alternate Contact (These individuals will also receive copies of all correspondence):

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<thead>
<tr>
<th>Add Line</th>
<th>Name</th>
<th>UA Net ID</th>
<th>Research Role</th>
<th>Institution</th>
<th>Email Address</th>
</tr>
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<tr>
<td>Delete Line</td>
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* List all additional Research Personnel on the Research Personnel Form and attach with your submission

General Information

What is the expected length of this project?

Is this an Investigator-initiated study?  ☐ Yes  ☐ No

Are we participating in a multi-site study?  ☐ Yes  ☐ No

Will the University of Arizona be the IRB of Record for multiple sites?  ☐ Yes  ☐ No

Is the research utilizing a single IRB for review that is not the UA IRB?  ☐ Yes  ☐ No

Is this project strictly a review of data or specimens? No recruitment, interaction, or consent?  ☐ Yes  ☐ No

Does this project involve investigating a Drug, Device or Biologic?  ☐ Yes  ☐ No

Does this project involve medical procedures which the PI is not licensed to conduct?  ☐ Yes  ☐ No

Is this project a Clinical Trial?

* A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Funding Information

Will the project be supported by any funding?  ☐ Yes  ☐ No

Location of Research

☐ Banner - University Medical Center
☐ University of Arizona Cancer Center
☐ University of Arizona Campus
☐ Data Warehouse
☐ Outside the US
☐ Online
☐ Other
Application for Human Research

Financial Conflict of Interest Disclosure

In order to submit this application, each Investigator must complete the University’s Conflict of Interest (“COI”) requirements. 

*To be up-to-date, an Investigator must have submitted a disclosure through the COI Disclosure System since the prior June 1.

If you are filling this out on behalf of other investigators, you will need to confirm the answers to this and any following COI questions in this form directly with each Investigator. Each Investigator can log on to the COI Disclosure System to view the current status of their disclosures. For an overview of the COI disclosure process for IRB submissions, see the COI FAQ webpage.

1. Is each Investigator on the project up-to-date with COI disclosures?  
   - Yes  
   - No

2. Has any Investigator disclosed any outside financial or personal interest though the COI Disclosure System?
   - Yes  
   - No

3. Is a drug, device or other investigational product being used or evaluated in this project?  
   - Yes  
   - No

---

Project Abstract

Background: Provide the scientific or scholarly background for the proposed Human Research. Discuss relevant prior experience or preliminary data (e.g., existing literature). (Limit 10000 Characters including spaces)

Purpose: Describe the purpose, specific aims, objectives, questions to be answered, hypotheses, and/or primary and secondary study endpoints of the Human Research.

Lay Summary: Provide a brief description of the proposed research using terms that someone who is not familiar with the science or your discipline can understand. (Limit 2000 Characters including spaces)

Resources: Describe the resources (personnel, facilities, time, emergency resources, etc.) available to recruit, consent, conduct study procedures, and analyze data.

---

Population & Recruitment

Maximum number of participants to be enrolled in the study:

Please check all the categories of participants that will be included in the research:

- [ ] Children (1-17 yrs old)  
- [ ] Cognitively Impaired Subjects  
- [ ] Adults  
- [ ] Native Americans  
- [ ] Pregnant Woman/Neonates (0-2 yrs old)
- [ ] Prisoners  
- [ ] Refugees  
- [ ] UA Staff/Faculty  
- [ ] UA Students  
- [ ] Other – please explain below

What are the inclusion and exclusion criteria for study participation?

Indicate age range, gender, and ethnicity of your research population:

---
Please select the methods that will be used to recruit individuals. **Provide copies of documents, as applicable.**

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<tr>
<th>Method</th>
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<tbody>
<tr>
<td>Email</td>
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<td>Flyers</td>
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<td>TV, Radio, Print</td>
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<tr>
<td>In Person Presentations</td>
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<td>Face to Face</td>
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<td>Other – please explain below</td>
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</table>

**Explain the recruitment process:**

Where will recruitment take place?

When will recruitment occur? Provide a time frame with dates if applicable.

**Informed Consent**

Please indicate the informed consent process(es) and/or document(s) to be used in the study. Check all that apply. **Provide copies of documents, as applicable.**

| Consent Type                        | Form Type                      |   |
|-------------------------------------|--------------------------------|
| Informed Consent (ICF) – written form |                                |   |
| Assent (participants under 18) – written form |                                |   |
| Parental Permission – written form   |                                |   |
| Translated Consent/Assent – written form(s) |                                |   |
| Combined ICF/PHI Authorization- form  |                                |   |
| Exception From Informed Consent (EFIC) |                                |   |
| Debriefing Script                   |                                |   |
| Short Consent Form- written from     |                                |   |
| Informed Consent – oral script/online/unsigned |                                |   |
| Assent – oral script/online/unsigned |                                |   |
| Parental Permission – oral script/online/unsigned |                                |   |
| Translated Consent/ Assent- oral script/online/unsigned |                                |   |
| Waivers of consent or waiver or alteration of PHI |                                |   |
| Broad Consent for future research   |                                |   |
| Protected Health Information (PHI) Authorization-written form |                                |   |
| Other – please explain below        |                                |   |

**Describe in detail the consent processes checked above:**

**Data Collection Procedures**

Please select the methods of data collection that will be employed in this study (select all that apply):

<table>
<thead>
<tr>
<th>Method</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Audio/Video recording</td>
<td>Anthropometric measures (e.g., height, weight, waist circumference, etc.)</td>
</tr>
<tr>
<td>Benign Interventions</td>
<td>Biological Specimens (urine/feces, tissue, saliva, skin, hair, nails, nasal swab)</td>
</tr>
<tr>
<td>Biological Specimens- Blood Draws</td>
<td>Biological Specimens- Clinical discarded of blood or specimens</td>
</tr>
<tr>
<td>Clinical Data Warehouse</td>
<td>Cognitive or behavioral measures, including daily diaries (Note- if surveys will also be administered, please select the appropriate option above.)</td>
</tr>
<tr>
<td>CT Scans</td>
<td>Data previously collected for research purposes</td>
</tr>
<tr>
<td>Deception</td>
<td>Data collected using other communication/electronic devices (e.g., cell phones, pagers and texting devices)</td>
</tr>
<tr>
<td>Interviews- Focus groups</td>
<td>Interviews- In person</td>
</tr>
<tr>
<td>MRI/ Ultrasound with contrast</td>
<td>MRI/ Ultrasound without contrast</td>
</tr>
</tbody>
</table>
Participant Observation  Non-invasive instruments (e.g. external sensors applied to the body)
Screening Data  Self health monitoring (e.g., pedometers, food diaries, etc.)
Surveys- Paper  Surveys- Internet (including online and email based data collection)
Surveys- Telephone  Randomization with Control and Experimental Groups
Records- Billing  Records- Educational
Records- Employee  Records- Lab, pathology and/or radiology results
Records- Medical Review  Records- Mental Health
Records- Physician/Clinical  Records- Substance Abuse
Use of recombinant DNA  Use of Social Networking Sites
Use of Stem Cells  X-ray Scans
Other activities or interventions- Describe below

* Submit the appropriate approval from Biosafety Committee.

Please provide details of the research procedures and include the study population who will be completing them.

Please state the estimated time commitment for subject participation.

If "Biological Specimens" is checked above, please state the amount and frequency at which it will be collected?

Benefits, Costs, Compensation & Risks

Describe the anticipated benefits of this study to society, academic knowledge or both.

Describe any benefits that individuals may reasonably expect from participation.

Describe any costs, monetary and non-monetary, that subjects may incur.

Discuss the amount of compensation (monetary and/or non-monetary) subjects may receive. Describe if compensation will be prorated.

Please describe all physical, psychological, social, legal, and/or economic risk you feel are associated with participation in this research. NOTE: Risks not directly related to the research need not be included in this section.

Discuss what steps have been taken to minimize risk to subjects/data.

Describe the provisions for medical care and available compensation in the event of research related injury. If the Human Research has a clinical trial agreement, this language should reflect what is stated in the agreement.

Privacy and Confidentiality
Will the research team be accessing medical records, educational records or employee records during the research?  

☐ Yes  ☐ No

Where will the data be stored?

☐ REDCap  ☐ Clinical Data Warehouse
☐ Box@UA Health  ☐ Box@UA
☐ Password Protected Drive  ☐ Encrypted Drive
☐ External Drive (USB, Flash drive)  ☐ Department Drive
☐ Cloud Server  ☐ UA Records Management & Archives
☐ Departmental Office  ☐ Other – please explain below

For each of the storage location checked above, discuss the type of data to be stored (including if the data is identifiable), who may have access to the data, and how long the data will be kept.

*NOTE: You are responsible for following University policy and guidelines for proper transmission and storage of Confidential or Regulated Data, including PHI.

Will you be transmitting/receiving any subject data to/from an outside group?  ☐ Yes  ☐ No

Discuss how, when and why subjects/data may be removed from the study. If abrupt withdrawal is necessary, discuss how subjects will be withdrawn so that they are not put at increased risk. Discuss what happens if a subject is withdrawn from one part of the study but asked to continue with other parts, such as ongoing follow-up.

Describe steps, if any, to protect the privacy of the subjects throughout their participation in the Human Research (e.g. during the recruitment process, consent process, and/or research procedures).

Use of Data/Specimens

In which of the following formats will the data be stored?  ☐ Identifiable  ☐ Coded  ☐ De-Identified

What security controls (e.g. administrative, physical, technical) are in place to make sure data/specimens are secure?

Will data/specimens be kept for future research, including unspecified future research, genetics and/or whole genome sequencing?  ☐ Yes  ☐ No

Will subjects receive results for any future research?  ☐ Yes  ☐ No

Will the data/specimens be stored in a repository?  ☐ Yes  ☐ No

Will the data/specimens be shared with collaborating entities?  ☐ Yes  ☐ No

Will the data/specimens be sold to pharmaceutical companies?  ☐ Yes  ☐ No

Provide a brief lay discussion of the plan to monitor for subject safety, if applicable. Describe how the data will be evaluated, include a timeline of when the review(s) will occur, who will review the information, and what information will be reviewed. If there will not be a way to monitor for subject safety, please explain.

Remember to attach the following documentation to your submission email:
Application for Human Research

- PI/Co-PI CV or Biosketch
- List of Project Personnel
- Appendices (if applicable)
- Recruitment Material
- Informed Consent Documentation
- Data Collection Tools
- Email confirmations from Advisor (required for all students and residents), Scientific/Scholarly Reviewer and Department Head.

Principal Investigator

I certify that the information I provide in this application is correct and complete.

☐ Attestation of Principal Investigator

_____________________________________________ Date

Typed name of Principal Investigator

Scientific/Scholarly Review (See HSPP Guidance on requirements for Scientific/Scholarly Assessment)

☐ Nationally based, federal funding organization (NIH, NSF) subject to full peer review
☐ Nationally based, non-federal funding organization (March of Dimes, Amer Academy of Pediatrics) subject to peer review
☐ Locally constituted peer review (signature required)

Department/Center/Section Review

I have reviewed this application and determined that all departmental requirements are met and that the investigator has adequate resources to conduct the Human Research.

_____________________________________________ Date

Signature of Department/ Center/Section Review

Print Name and Title

NOTE: Actual signature is not required. The HSPP Office will accept either email confirmation or an actual signature. This means that all signatures might not be on the same document. Attach email confirmations with your submission.

You have now completed this form. Next steps:

1) Please save a copy of this document for your records.

2) Once it is ready email the application and attach all additional documents to vpr-irb@email.arizona.edu. Please
Amendment of Approved Human Research

**Request to amend previously approved research**

<table>
<thead>
<tr>
<th>IRB Project No.:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Title:</td>
<td></td>
</tr>
<tr>
<td>Investigator:</td>
<td></td>
</tr>
<tr>
<td>Investigator's Contact Information:</td>
<td>Phone/Official University Email:</td>
</tr>
<tr>
<td>Alternate Contact:</td>
<td></td>
</tr>
<tr>
<td>Alternate Contact's Information:</td>
<td>Phone/Official University Email:</td>
</tr>
</tbody>
</table>

**SECTION 1: Summarize all requested changes in lay language (limited to 2000 characters including spaces):**

Provide the rationale for the requested changes:

Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:

<table>
<thead>
<tr>
<th>Does this amendment change the risk/benefit ratio? If yes, how?</th>
<th>□ No</th>
<th>□ Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has this amendment already been implemented? If yes, how?</td>
<td>□ No</td>
<td>□ Yes</td>
</tr>
<tr>
<td>Has there been a change in funding? If yes, complete below:</td>
<td>□ No</td>
<td>□ Yes</td>
</tr>
<tr>
<td>a. Funding PI:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Proposal Title:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Funder Name:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Total funding amount OR per subject amount:</td>
<td></td>
<td></td>
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</tbody>
</table>

- Submit this form and all applicable new and/or revised research materials affected by the changes (recruitment, consent, data collection, permissions/approvals, etc.). All revised materials must be submitted with proposed changes clearly outlined (e.g., using track changes in Word).

- For changes to research personnel at this time, please use Amendment of Key Personnel Form and include a (track changed) Research Personnel form list.
**Amendments must be submitted separately from the Continuing Review.**

<table>
<thead>
<tr>
<th>IRB Project No.:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiration Date:</td>
</tr>
<tr>
<td>Project Title:</td>
</tr>
<tr>
<td>Investigator:</td>
</tr>
<tr>
<td>Investigator's Contact Information: Phone/Official University Email:</td>
</tr>
<tr>
<td>Alternate Contact:</td>
</tr>
<tr>
<td>Alternate Contact's Information: Phone/Official University Email:</td>
</tr>
</tbody>
</table>

**SECTION 1: BRIEF ABSTRACT OF THE HUMAN RESEARCH:**

**SECTION 2: CURRENT PROTOCOL STATUS**  
Check all that apply

- **a.** Enrollment in progress or still planned (please send **only** word version of the consent(s) if applicable)
- **b.** The research is permanently closed to enrollment (including the addition of new records or specimens from people not previously "enrolled" on chart review or specimen-only studies)
- **c.** All subjects have completed all research-related interventions and/or interactions
- **d.** The research remains active only for long-term follow-up of subjects
- **e.** Collection of private identifiable information is completed
- **f.** The remaining research activities are limited to identifiable data analysis. NOTE: If all enrollment, treatment, follow-up and data analysis of identifiable data are completed the project may be concluded - submit Closure instead.
SECTION 3: ENROLLMENT STATUS: Please complete the following table related to enrollment of participants in your study. For definitions and guidance on how to determine enrollment, see HRPP Guidance, Enrollment and Accrual of Study Participants.

“Approval period” means the time since initial approval (if this is the first continuing review for the project) or since the last continuing review approval.

<table>
<thead>
<tr>
<th>Max IRB Approved:</th>
<th>Since initial activation:</th>
<th>During last approval period:</th>
<th>Male (total since initial activation)</th>
<th>Female (total since initial activation)</th>
<th>Other/Unknown (total since initial activation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants enrolled in the study locally:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of participants enrolled at all sites (if available; only for multi-site research):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4: STATUS REPORT ON THE PROGRESS OF THE HUMAN RESEARCH:

1. Status of subjects consented into this study (describe if subject consenting is completed, number of and whether any subjects were screen failures, or whether any subjects withdrew from the research and the reason why):

2. Status of achieving the aims of the human research:

3. Expected progress to be made during the next approval period:

4. A thorough summary of any new and relevant information, published or unpublished, since the last approval period ("Last approval period" means the time since initial or continuing review, whichever is most recent), especially information about risks associated with the research, please note N/A is not accepted by the IRB:
SECTION 5: QUESTIONNAIRE

- For Questions 1-10, attach a summary explanation or description for each question whose answer is "Yes." Summaries are not required for "No" answers.
- "Last approval period" means the time since initial or continuing review, whichever is most recent.

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>During the last approval period, have subjects experienced harms (expected or unexpected)?</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>During the last approval period, have subjects experienced any benefits?</td>
<td></td>
</tr>
</tbody>
</table>
| 3. | During the last approval period, have there been any reportable information items, including unanticipated problems involving risks to subjects or others?  
 | Date of IRB Approval | Brief description of reportable item |
| 4. | During the last approval period, have any subjects withdrawn from the research? |
| 5. | During the last approval period, have any subjects or others complained about the research? |
| 6. | During the last approval period, have there been any interim findings, multi-center trial reports; sponsor/monitor findings or reports; or data safety monitoring board reports? If Yes, provide a copy of the findings or report. |
| 7. | In the opinion of the principal investigator, have the risks or potential benefits of this research changed? |
| 8. | During the last approval period, have there been any amendments to the research?  
 | Date of IRB Approval | Brief description of amendment |
| 9. | Have any problems that required prompt reporting NOT been submitted as required? |
| 10. | During the last approval period, have there been any changes in funding to the research?  
 | Date of IRB Approval | Brief description of amendment |

Provide 1 copy of the following:
- Approved consent documents (in Word) to be used in the next approval period (including HIPAA authorization documents, if applicable). This may be omitted if the research is permanently closed to enrollment and if re-consent is not needed.
• Approved script of information to be provided orally to subjects if consent will not be documented in writing. This may be omitted if the research is permanently closed to enrollment and if re-consent is not needed.

• Summary regarding any "Yes" answers from Section 5; questions 1-12 above.
Instructions
This consent form/disclosure form is for research that is not funded, does not collect any biospecimens or will not access HIPAA protected information, and is limited to research that is minimal risk in nature. Delete the RED text and instruction comments prior to the submission. Additional language, as appropriate, are in comments. The document should generally be at the 6th-8th grade reading level, and the content should be aligned with information in your Project Narrative.

Consent to Participate in Research

Study Title:
Principal Investigator:

You are being asked to participate in a research study. Your participation in this research study is voluntary and you do not have to participate. This document contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Provide a brief explanation of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This summary should include:

- The purpose and expected duration
- Requirements of study participation
- A summary of the risks and/or benefits, if any

There are no expected risks to you as a result of participating in this study. You will not benefit directly from participating in this study.

- Other alternatives to participating, if appropriate
- Time commitment
- Payment to subjects, including extra credit, any prorated amounts
- Confidentiality of information - Describe whether and how identifiable information will be de-identified, and if it will be shared with other researchers for this research or future research.

{Describe the way you will maintain the confidentiality of records that identify the subject. Use words to the following effect, if appropriate:} Your name will not be used in any report.
Identifiable research data will be encrypted and password protected.

{If you will be coding the data:} Your responses will be assigned a code number. The list connecting your name to this code will be kept in an encrypted and password protected file. Only the research team will have access to the file. When the study is completed and the data have been analyzed, the list will be destroyed.

{If you are using an audio or video recording, or photographs in the study, describe if and when such materials will be destroyed}: With your permission, I would like to audiotape this interview so that I can make an accurate transcript. Once I have made the transcript, I will erase the recordings. Your name will not be in the transcript or my notes.

{For a focus group:} You will not be identified in any report or publication of this study. Even though we will tell all participants in the study that the comments made during the focus group should be kept confidential, it is possible that participants may repeat comments outside the group.

{If the study will be anonymous, use words to the following effect:} The information that you give in the study will be anonymous. Your name will not be collected or linked to your answers.

{If it is possible to deduce the participant’s identity through their responses, state the following:} Because of the nature of the data, it may be possible to deduce your identity; however, there will be no attempt to do so and your data will be reported in a way that will not identify you.

{If the information will be shared:} Information that may identify you may be used for future research or shared with another researcher for future research studies without additional consent. [Explain]

{OR}
Information that identifies you will only be used for future research or shared with another researcher after obtaining your consent. [Explain]

{OR} Information collected about you will not be used or shared for future research studies.

{Required} The information that you provide in the study will be handled confidentially. However, there may be circumstances where this information must be released or shared as required by law. Northern Arizona University Institutional Review Board may review the research records for monitoring purposes.
• Who to call for questions:

For questions, concerns, or complaints about the study you may contact ________________.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Research Protection Program at 928-523-9551 or online at http://nau.edu/Research/Compliance/Human-Research/Welcome/.

Signatures are required as determined by the IRB. For many studies involving focus groups, observations, and on-line surveys it may not be necessary to obtain a signature from participants. Use this signature line when you will be obtaining written consent.

AGREEMENT TO PARTICIPATE

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I affirm that I am at least 18 years of age and voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject _______________________________ Signature of subject _______________________________ Date __________________

AGREEMENT TO BE AUDIORECORDED
(delete if NOT applicable)

Subject Signature: _______________________________ Date: ______________

AGREEMENT TO BE VIDEORECORDED
(delete if NOT applicable)

Subject Signature: _______________________________ Date: ______________
Some studies may require signature of PI or research staff. This is an optional section.
(delete if NOT applicable)

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent: ________________________________

Signature: ________________________________ Date: _______
Instructions
This consent form is only for research that does not collect any biospecimens or will not access HIPAA protected information. Instructions are in red and suggested language in black. Delete all red text and instruction comments prior to submission. Additional language, as appropriate, are in comments. The document should generally be at the 6th-8th grade reading level, and the content should be aligned with information in your Project Narrative.

Consent to Participate in Research

Study Title:
Principal Investigator:
Sponsor (delete if not funded):

Summary of the research
This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

If your consent is more than 4 pages, provide a brief explanation of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This presentation of information is to be short, and can summarize information explained later in greater detail. It is NOT necessary to repeat information provided in the summary. This summary should include:

- The purpose and expected duration
- Major requirements of the study
- The most important risks and/or benefits
- Other alternatives to participating, if appropriate
- Time commitment

Why is this study being done?
Explain this is a research study. Describe the purpose of the research.

What will happen if I take part in this study?
Explain the procedures to be done. Specifically identify any procedures that are for research only.
If educational records will be accessed:
• Specify the records that may be disclosed;
• State the purpose of the disclosure; and
• Identify the party or class of parties to whom the disclosure may be made.

**How long will I be in the study?**
Explain the expected duration of the subject's participation.

**How many people will take part in this study?**
Identify the approximate number of subjects you plan to enroll in the study, both total (study-wide) and local (if different).

**Can I stop being in the study?**
Explain that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If applicable, explain what may happen and what procedures are required for orderly withdrawal or termination if the subject leaves the study early, or is withdrawn from the study by the researcher.

**What risks or benefits can I expect from being in the study?**
Explain any reasonably foreseeable risks or discomforts to the subjects as a result of participation from the research. Explain any expected benefits to subjects. If there are alternatives to participating, describe them here.

If applicable, explain that any significant new findings found during the course of the research that may relate to the subject’s willingness to continue will be provided to them.

**Will I be paid for participating in the study or experience any costs?**
Explain if a participant will receive any compensation or extra credit from their participation in the research. Discuss the amount and timing, including a description of any proration, of any compensation (monetary and/or non-monetary such as extra credit).

If applicable, explain if the participant may have any costs as a result of participating in the study. Any additional costs to the subject from participating may include subject’s time or transportation.
EXAMPLE:

You will receive $20.00 for taking part in this study according to the following schedule:

- $5.00 at your first visit
- $5.00 at your second visit
- $10.00 at your third visit

Will my study-related information be kept confidential?
Describe the way you will maintain the confidentiality of records.
Specify the entity(ies) which would potentially have access to research files.

The information that you provide in the study will be handled confidentially. However, there may be circumstances where this information must be released or shared as required by law. The Northern Arizona University Institutional Review Board; other federal, state, or international regulatory agencies; or the sponsor of the study, if any, may review the research records for monitoring purposes.

Will my study-related information be used for future research?
Use one of the following statements if collecting identifiable data or biospecimens:

Information that may identify you may be used for future research or shared with another researcher for future research studies without additional consent. [Explain]

{OR}
Information that identifies you will only be used for future research or shared with another researcher after obtaining your consent. [Explain]

{OR} Information collected about you will not be used or shared for future research studies.

Who can answer my questions about the study?
For questions, concerns, or complaints about the study you may contact ____________.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Research Protection Program at 928-523-9551 or online at http://nau.edu/Research/Compliance/Human-Research/Welcome/.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact ________________.
Signatures are required as determined by the IRB. For many studies involving focus groups, observations, and on-line surveys, it may not be necessary to obtain a signature from participants. Use this signature line when you will be obtaining written consent.

AGREEMENT TO PARTICIPATE

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I affirm that I am at least 18 years of age and voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject __________________________ Signature of subject __________________________ Date ___________

AGREEMENT TO BE AUDIORECORDED
(delete if NOT applicable)

Subject Signature: __________________________________________ Date: ___________

AGREEMENT TO BE VIDEORECORDED
(delete if NOT applicable)

Subject Signature: __________________________________________ Date: ___________

Some studies may require signature of PI or research staff. This is an optional section.
(delete if NOT applicable)

Investigator/Research Staff

I have explained the research to the participant or the participant’s representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant’s representative.

Printed name of person obtaining consent __________________________ Signature of person obtaining consent __________________________ Date ___________

Consent Version: MM/DD/YYYY
Instructions
This consent form is for biomedical research, including collection of biospecimens. Delete all red text and instruction comments prior to the submission. Additional language, as appropriate, are in comments. The document should generally be at the 6th-8th grade reading level, and the content should be aligned with information in your Project Narrative.

Consent to Participate in Research

Study Title:

Principal Investigator:

Sponsor (delete if not funded):

Summary of the research
This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Provide a brief explanation of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This presentation of information is to be short, and can summarize information explained later in greater detail. It is NOT necessary to repeat information provided in this summary. This summary may be a page or more, depending on the study. This summary should include:

- The purpose and expected duration
- Major requirements of the study
- The most important risks and/or benefits
- Other alternatives to participating, if appropriate
- Time commitment

[If applicable]: The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.

Why is this study being done?
Explain the purpose of the study and a statement that the study involves research.

What will happen if I take part in this study?
Explain the procedures to be done. Specifically identify any procedures that are for research only. Include:

- The probability for random assignment to each treatment
- The subject’s responsibilities

How long will I be in this study?
Explain the expected duration of the subject's participation.

How many people will take part in this study?
Identify the approximate number of subjects you plan to enroll in the study, both total (study-wide) and local (if different).

What benefits can I expect from being in this study?
Explain any reasonably expected benefits to subject or others.

- When there is no intended clinical benefit to the subject, a statement to this effect
- Do not include statements of unproven claims of effectiveness or certainty of benefit, either implicit or explicit

What risks, side effects or discomforts can I expect from being in the study?
Explain any reasonably foreseeable risks or discomforts to the subjects as a result of participation or procedures from the research. Explain, if applicable, that a particular treatment or procedure may involve risks that are currently unknown or foreseeable.

Explain that if there are significant new findings that may impact a subject’s participation, they will be informed.

What other choices do I have if I do not take part in this study?
Explain that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Describe any appropriate alternative procedures or courses of treatment. For some studies, the only alternative would be to not participate.

When may participation in the study be stopped?
Under what circumstances the subject’s participation may be stopped by the investigator, the consequences of a subject’s decision to withdraw from the research, and the procedures for orderly withdrawal of participation by the subject.

What happens if I am injured because I took part in this study?
For research involving more than minimal risk, include the following elements:
- An explanation as to whether any compensation is available if injury occurs
- An explanation as to whether any medical treatments are available if injury occurs
  If compensation and/or treatment is available: what comprises that compensation and/or treatment, or where further information may be obtained

Northern Arizona University has no funds set aside for the payment of treatment expenses for this study.

What are the costs of taking part in this study?
Explain who will pay for the study procedures and/or medications required for participation. If third party payers are expected to pay for standard care treatment, and identify what the subject will be responsible for.

Will I be paid for taking part in this study?
Discuss the amount and timing, including a description of any proration, of any compensation (monetary and/or non-monetary).

EXAMPLE:
You will receive $ 20.00 for taking part in this study according to the following schedule:

- $ 5.00 at your first visit
- $ 10.00 at your second visit
- $ 5.00 at your third visit

Compensation for participation in a research study is considered taxable income for you. We are required to obtain your name, address, and Social Security number for federal tax reporting purposes. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes.

Will my data or specimens be stored for future research?
The consent must include either:
• A statement that identifiers might be removed from the private information or biospecimens, and that after such removal, the information or biospecimens may be used for future research studies without additional informed consent [Include a description of what information/specimens will be stored and whom they will be shared with (both internal or outside the institution). Explain what research may be conducted with these data/specimens - including unspecified future research, genetics, disease specific, etc.]; or

• A statement that the identifiable information or biospecimen, even if identifiers are removed, will not be used or distributed for future research.

Will my specimens be sold for commercial profits?
Describe whether subjects will or will not share in any commercial profit from the use of their biospecimens, even if identifiers are removed.

Will I hear back on any results that directly impact me?
Describe whether any clinically relevant results will be disclosed to subjects, and if so, under what conditions.

Will Whole Genome Sequencing be done with my specimen?
Describe, if known, whether whole genome sequencing will be done.

Will my study-related information be shared, disclosed, and kept confidential?
Specify the extent, if any, to which confidentiality of identifiable records will be maintained. Specify the entity(ies) which would potentially share or have access to research files, and remove those that are not applicable.

Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups may include:

• Office for Human Research Protections, Food and Drug Administration, or other federal, state, or international regulatory agencies
• Northern Arizona University Institutional Review Board
• The sponsor supporting the study, their agents or study monitors

Use this language when there is additional optional research

Optional Research Activity
Optional research activity is part of this project. If you choose to participate in this optional activity your information shall be included for this optional activity.
Who can answer my questions about this study?

If at any time you feel you have had a research-related injury, or for questions, concerns, or complaints about the study you may contact ____________.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Research Protection Program at 928-523-9551 or online at http://nau.edu/Research/Compliance/Human-Research/Welcome/.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact ________________.

(If Applicable): A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

______________________________

AGREEMENT TO PARTICIPATE

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I affirm I am at least 18 years old and voluntarily agree to participate in this study. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form.

_________ ___________ ___________
Printed name of subject Signature of subject Date

If you are enrolling minors or individuals who have a legally authorized representative (LAR), include this section.

_________ ___________ ___________
Printed name of person authorized to consent for subject (when applicable) Signature of person authorized to consent for subject (when applicable) Date

______________________________

NAU Adult Consent Biomedical
V Jan 2019
AGREEMENT TO BE AUDIORECORDED
(delete if NOT applicable)

Subject Signature: ____________________________ Date: ________________

AGREEMENT TO BE VIDEORECORDED
(delete if NOT applicable)

Subject Signature: ____________________________ Date: ________________

Some studies may require signature of PI or research staff. This is an optional section.

Investigator/Research Staff

I have explained the research to the participant or the participant’s representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant’s representative.

Printed name of person obtaining consent ____________________________ Signature of person obtaining consent ____________________________ Date ________________
Instructions

This consent form is for medical research, including collection of biospecimens or research that will access HIPAA protected information. Delete all red text and instruction comments prior to the submission. Additional language, as appropriate, are in comments. The document should generally be at the 6th-8th grade reading level, and the content should be aligned with information in your Project Narrative. Grey highlighted text in the template below is required if conducting research that collects HIPAA protected information.

Consent to Participate in Research

Study Title:

Principal Investigator:

Sponsor (delete if not funded):

Summary of the research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Provide a brief explanation of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This presentation of information is to be short, and can summarize information explained later in greater detail. It is NOT necessary to repeat information provided in the summary. This summary may be a page or more, depending on the study. This summary should include:

- The purpose and expected duration
- Major requirements of the study
- The most important risks and/or benefits
- Other alternatives to participating, if appropriate
- Time commitment

[If applicable]: The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.

Why is this study being done?

Explain the purpose of the study and a statement that the study involves research.
What will happen if I take part in this study?
Explain the procedures to be done. Specifically identify any procedures that are for research only. Include:

- The probability for random assignment to each treatment
- The subject’s responsibilities

How long will I be in this study?
Explain the expected duration of the subject's participation.

How many people will take part in this study?
Identify the approximate number of subjects you plan to enroll in the study, both total (study-wide) and local (if different).

What benefits can I expect from being in this study?
Explain any reasonably expected benefits to subject or others.

- When there is no intended clinical benefit to the subject, a statement to this effect
- Do not include statements of unproven claims of effectiveness or certainty of benefit, either implicit or explicit

What risks, side effects or discomforts can I expect from being in the study?
Explain any reasonably foreseeable risks or discomforts to the subjects as a result of participation or procedures from the research. Explain, if applicable, that a particular treatment or procedure may involve risks that are currently unknown or foreseeable.

Explain that if there are significant new findings that may impact a subject’s participation they will be informed.

What other choices do I have if I do not take part in this study?
Explain that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Describe any appropriate alternative procedures or courses of treatment. For some studies, the only alternative would be to not participate.

When may participation in the study be stopped?
Under what circumstances the subject’s participation may be stopped by the investigator, the consequences of a subject’s decision to withdraw from the research, and the procedures for orderly withdrawal of participation by the subject.

**What happens if I am injured because I took part in this study?**

For research involving more than minimal risk, include the following elements:

- An explanation as to whether any compensation is available if injury occurs
- An explanation as to whether any medical treatments are available if injury occurs
- If compensation and/or treatment is available: what comprises that compensation and/or treatment, or where further information may be obtained

Northern Arizona University has no funds set aside for the payment of treatment expenses for this study.

**What are the costs of taking part in this study?**

Explain who will pay for the study procedures and/or medications required for participation. If third party payers are expected to pay for standard care treatment, and identify what the subject will be responsible for.

**Will I be paid for taking part in this study?**

Discuss the amount and timing, including a description of any proration, of any compensation (monetary and/or non-monetary).

**EXAMPLE:**

You will receive $20.00 for taking part in this study according to the following schedule:

- $5.00 at your first visit
- $5.00 at your second visit
- $10.00 at your third visit

Compensation for participation in a research study is considered taxable income for you. We are required to obtain your name, address, and Social Security number for federal tax reporting purposes. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes.

**Will my data or specimens be stored for future research?**

The consent must include either:
• A statement that identifiers might be removed from the private information or biospecimens, and that after such removal, the information or biospecimens may be used for future research studies without additional informed consent [Include a description of what information/specimens will be stored and whom they will be shared with (both internal or outside the institution). Explain what research may be conducted with these data/specimens - including unspecified future research, genetics, disease specific, etc.]; or

• A statement that the identifiable information or biospecimen, even if identifiers are removed, will not be used or distributed for future research.

**Will my specimens be sold for commercial profits?**
Describe whether subjects will or will not share in any commercial profit from the use of their biospecimens, even if identifiers are removed.

**Will I hear back on any results that directly impact me?**
Describe whether any clinically relevant results will be disclosed to subjects, and if so, under what conditions.

**Will Whole Genome Sequencing be done with my specimen?**
Describe, if known, whether whole genome sequencing will be done.

**Will my study-related information be shared, disclosed, and kept confidential?**
Specify the extent, if any, to which confidentiality of identifiable records will be maintained. Specify the entity(ies) which would potentially share or have access to research files, and remove those that are not applicable.

> It is anticipated that there will be circumstances where your study related information and Protected Health Information (PHI) will be released to persons and organizations described in this form. If you sign this form, you give permission to the research team to use and/or disclose your PHI for this study. Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups may include:

- Office for Human Research Protections, Food and Drug Administration, or other federal, state, or international regulatory agencies
- **LIST HOSPITAL OR CLINIC ENTITY HERE**
- Northern Arizona University Institutional Review Board
- The sponsor supporting the study, their agents or study monitors
- Your primary care physician or a specialist taking care of your health.
Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?
Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

- Specify what PHI, including specific data elements that will be used.

Demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number. If you receive compensation for participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.

Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and study sponsor’s monitor may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

When will my authorization expire?
There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

Do I have to sign this authorization form?
You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; and it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

*Use this language when future research is NOT optional*
Also, by signing this form you are authorizing and permitting uses and/or disclosures of your PHI for future research purposes (e.g., future studies) as described in this document.

*Use this language when there is additional optional research*
Optional Research Activity
Optional research activity is part of this project. If you choose to participate in this optional
activity your PHI shall be included for this optional activity.

By initialing the line below, you agree to allow your PHI to be used and/or disclosed for the optional Study activity referenced above.

_____ Initials

**Use this language when future research is optional**

**Future Use of PHI**

Future research activity is part of this project. If you choose to participate in the future research activity your PHI will be included in this future research activity.

By initialing the line below you agree to allow your information to be used and/or disclosed for the optional future research referenced above.

_____ Initials

**What do I need to know if I decide to cancel my authorization?**

After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. Contact information is under “Who can answer my questions about the study” at the end of this document.

**Will access be limited to your research study record during this study?**

You may not have access to the research information developed as part of this study until it is completed.

**Who can answer my questions about this study?**

If at any time you feel you have had a research-related injury, or for questions, concerns, or complaints about the study you may contact ____________.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Research Protection Program at 928-523-9551 or online at http://nau.edu/Research/Compliance/Human-Research/Welcome/.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact ________________.
If you have any questions or concerns about the authorization for access to your PHI, you should contact LIST HOSPITAL OR CLINIC CONTACT INFORMATION. You may also request and will be provided a copy of the Notice of Privacy Practices.

To cancel your authorization for access to PHI you must notify the Principal Investigator/Research Team in writing at the following address:

Insert address for Investigator

(If Applicable): A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AGREEMENT TO PARTICIPATE

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study and I authorize the use and/or disclosure of my PHI. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form.

Printed name of subject __________________________ Signature of subject __________________________ Date ____________

If you are enrolling minors or individuals who have a legally authorized representative (LAR), include this section.

Printed name of person authorized to consent for subject (when applicable) __________________________ Signature of person authorized to consent for subject (when applicable) __________________________ Date ____________

Relationship to the subject __________________________

AGREEMENT TO BE AUDIORECORDED

(delete if NOT applicable)

Subject Signature: __________________________ Date: ____________
AGREEMENT TO BE VIDEORECORDED
(delete if NOT applicable)

Subject Signature: __________________________ Date: ____________

Some studies may require signature of PI or research staff. This is an optional section.

Investigator/Research Staff
I have explained the research to the participant or the participant’s representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant’s representative.

Printed name of person obtaining consent  Signature of person obtaining consent  Date
Consent to Participate in Research

Study Title:
Principal Investigator:

You are being asked to allow your child to participate in a research study. Your child’s participation in this research study is voluntary and your child does not have to participate. This document contains important information about this study and what to expect if you decide to allow your child to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to allow your child to participate.

Provide a brief explanation of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This summary should include:

- The purpose and expected duration
- Requirements of study participation
- A summary of the risks and/or benefits, if any

There are no expected risks to your child as a result of participating in this study. Your child will not benefit directly from participating in this study.

- Other alternatives to participating, if appropriate
- Time commitment
- Payment to subjects, including any prorated amounts
- Confidentiality of information - Describe whether and how identifiable information will be de-identified, and if it will be shared with other researchers for this research or future research.

(Describe the way you will maintain the confidentiality of records that identify the subject. Use words to the following effect, if appropriate:) Your child’s name will not be used in any report. Identifiable research data will be encrypted and password protected.
If you will be coding the data:) Your child’s responses will be assigned a code number. The list connecting your child’s name to this code will be kept in an encrypted and password protected file. Only the research team will have access to the file. When the study is completed and the data have been analyzed, the list will be destroyed.

If you are using an audio or video recording, or photographs in the study, describe if and when such materials will be destroyed: With your permission, I would like to audiotape your child’s interview so that I can make an accurate transcript. Once I have made the transcript, I will erase the recordings. Your child’s name will not be in the transcript or my notes.

For a focus group:) Your child will not be identified in any report or publication of this study. Even though we will tell all participants in the study that the comments made during the focus group should be kept confidential, it is possible that participants may repeat comments outside the group.

If the study will be anonymous, use words to the following effect:) The information that your child gives in the study will be anonymous. Your child’s name will not be collected or linked to their answers.

If it is possible to deduce the participant’s identity through their responses, state the following:) Because of the nature of the data, it may be possible to deduce your child’s identity; however, there will be no attempt to do so and your child’s data will be reported in a way that will not identify them.

If the information will be shared:) Information that may identify your child may be used for future research or shared with another researcher for future research studies without additional consent. [Explain]

OR
Information that identifies your child will only be used for future research or shared with another researcher after obtaining your permission. [Explain]

OR Information collected about your child will not be used or shared for future research studies.

Required) The information that your child provides in the study will be handled confidentially. However, there may be circumstances where this information must be released or shared as required by law. Northern Arizona University Institutional Review Board may review the research records for monitoring purposes.
• Who to call for questions:

For questions, concerns, or complaints about the study you may contact ________________.

For questions about your child’s rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Research Protection Program at 928-523-9551 or online at http://nau.edu/Research/Compliance/Human-Research/Welcome/.

Signatures are required as determined by the IRB. For many studies involving focus groups, observations, and on-line surveys it may not be necessary to obtain a signature from participants. Use this signature line when you will be obtaining written consent.

AGREEMENT TO PARTICIPATE
I have read (or someone has read to me) this form, and I am aware that I am being asked to allow my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I affirm that I am at least 18 years of age and agree to give permission for my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of parent/LAR  Signature of parent/LAR  Date

Printed name of subject  Relationship to subject  Date

AGREEMENT TO BE AUDIORECORDED
(delete if NOT applicable)

Parental/LAR Signature: ________________________________  Date: ______________

AGREEMENT TO BE VIDEORECORDED
(delete if NOT applicable)
Parental/LAR Signature:______________________________ Date:____________

Some studies may require signature of PI or research staff. This is an optional section. 
(delete if NOT applicable)

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:______________________________

Signature:______________________________ Date: ______
Assent form for Research Involving Young Minors (ages 8 and below)

In research with children or other participants for whom the ability to give informed consent may be otherwise compromised, it is usually appropriate to obtain some form of agreement, or "assent" to participation in the data collection sessions. For example, even though children or individuals with developmental disabilities may not be able to provide informed consent for participation in research, a researcher should still describe the procedures in language that can be understood by the subjects, and obtain their verbal "agreement" to participate. If an assent procedure is to be used, a prototype of the "script" of this procedure should be included in the appendices of the application.

The child assent is something children may not sign, depending on their age and maturity. The main thing is to explain what you want to do and also make sure the children understand that they can choose not to participate and even if they decide to participate, they can quit anytime they want. This explanation is usually read or otherwise given orally at a language level that the children would understand.

For example, "Verbal explanation of the project to the children" means what you say to the children when you explain what it is you want them to do. Some projects that deal with children, particularly those that do not take place as a regular classroom activity, must be described to the children at a language level that the children would understand.

You may use the example that follows as a model. Modify the language to fit your research procedures.

"I’d like to find out what you think about ______________, so I would like you to join in some discussion groups that will meet for about _____ minutes _____ a week for the next ______ weeks. I would like to ask some questions about (your experiences and feelings and how you think these things affect how you feel about) _____________ . If you don’t feel like answering any questions, you don’t have to, and you can stop talking with me anytime and that’s okay. I will be happy to answer any questions you have now or when we are talking together. Do you want to take part in this project?"

I, ______________________________, understand that my parent or legal guardian have said it's okay for me to take part in a research study about [FILL IN] with [NAME OF INVESTIGATOR.]

I know I have a choice not to take part and I have been told that I may stop at any time. If I say ‘No’, it will not be a bad thing.

_________________________________________  Date ______________________
Signature of Minor, OR

Printed Name __________________________________________________________

Assent Version Jan 2019
Assent Procedures for Middle Aged (generally age 9-15) Minors in Research

In research with children or other participants for whom the ability to give informed consent may be otherwise compromised, it is usually appropriate to obtain some form of agreement, or "assent" to participation in the data collection sessions. For example, even though children or individuals with developmental disabilities may not be able to provide informed consent for participation in research, a researcher should still describe the procedures in language that can be understood by the subjects, and obtain their agreement to participate. If an assent procedure is to be used, a prototype of the "script" of this procedure should be included in the appendices of the application.

The main thing is to explain what you want to do and also make sure the children understand that they can choose not to participate and even if they decide to participate, they can quit anytime they want. This explanation is usually read or otherwise given orally at a language level that the children would understand.

For example, "Verbal explanation of the project to the children" means what you say to the children when you explain what it is you want them to do. Some projects that deal with children, particularly those that do not take place as a regular classroom activity, must be described to the children at a language level that the children would understand.

You may use the example that follows as a model. Modify the language to fit your research procedures.

Instructions
This assent form/disclosure form is for use with minor participants (generally age 9-15). Delete the RED text before submitting this form to the IRB. Additional language, as appropriate, are in comments. The document should generally be at the 6th-8th grade reading level, and the content should be aligned with information in your IRB Application

Assent to Participate in Research

Study Title:  
Principal Investigator:  

- You are being asked to participate in a research study.  
- Your participation in this research study is voluntary.  
- You do not have to participate.
• This study is about X.
• You will be asked to do X.
• It will take X amount of time.
• Your [teacher, parents] will/will not know that you are in this study.
• You will receive a small amount of [money, gift] for the time you spend in the study.

If you decide you do not want to participate that is OK. Remember, you do not have to participate in the study if you do not want to.

Do you have questions?

Do you want to participate?

<table>
<thead>
<tr>
<th>Printed name of minor</th>
<th>Signature of subject</th>
<th>Date</th>
</tr>
</thead>
</table>

Some studies may require signature of PI or research staff. This is an optional section.
(delete if NOT applicable)

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent: _________________________________

Signature: _________________________________ Date: _______
Consent

If your research presents minimal risk to participants and involves no procedures for which written consent is normally required outside of the research context, you may convert your consent form into an information statement by deleting the participant’s signature line and the affirmation of age eligibility and receipt of a copy that appears below the signature line. Also, remove the section called “Refusal to Sign Consent and Authorization Section.” Then add to your information sheet the statement, “Completion of the survey indicates your willingness to participate in this project and that you are at least eighteen years old.” Use of an information statement would reduce your copies by one-half, since participants would keep their copy and not sign one to give to you. This would also further protect anonymity of participants. However, you may decide to use a signed consent form for your own records. It’s up to you.

Instructions are in blue and suggested language in black. Delete all blue sections prior to submittal.

You are being invited to participate in a research study titled [“Name of your study”]. This study is being done by [Name of Researcher(s)] from Northern Arizona University.

The purpose of this research study is [provide participants with a clear and accurate statement of the purpose of the research, use lay terms, do not repeat the study title]. If you agree to take part in this study, you will be asked to complete an online survey/questionnaire. This survey/questionnaire will ask about [insert topic of questions, especially if sensitive issues will be asked about, i.e. – alcohol/drug use, suicide, child abuse, etc.] and it will take you approximately [XX] minutes to complete.

You may not directly benefit from this research; however, we hope that your participation in the study may [describe societal benefits]. We believe there are no known risks associated with this research study; however, as with any online related activity the risk of a breach of confidentiality is always possible. To the best of our ability your answers in this study will remain confidential. We will minimize any risks by [describe how confidentiality will be secured, maintained, and how data will be disposed of].

Your participation in this study is completely voluntary and you can withdraw at any time. You are free to skip any question that you choose. If you choose not to participate it will not affect your relationship with Northern Arizona University or result in any other penalty or loss of benefits to which you are otherwise entitled.

If you have questions about this project or if you have a research-related problem, you may contact the researcher(s), [insert name(s) and phone number(s)]. If you have any questions concerning your rights as a research subject, you may contact Northern Arizona University IRB Office at irb@nau.edu or (928) 523-9551.

By submitting this survey, I affirm that I am at least 18 years of age and agree that the