

## TRIBAL RESEARCH ASSESSMENT CHECKLIST

The Tribal Research Assessment Checklist (TRAC) helps to ensure that a proposed research is appropriate for your community. At the end of TRAC, you will understand the protocol and have identified specific areas of concerns and will be able to make informed recommendations or requirements to the appropriate people (e.g., researcher, tribal council).

The purpose of TRAC is to assist tribes through 5 steps to assess the research protocol.

- I. Understand the research as written
- II. Obtain all relevant information and documents
- III. Assess study procedures
- IV. Assess risk of the research
- V. Assess benefits of the research

(An additional step III.X. to assess study procedures for research involving specimen collection is provided at the end of the checklist to be used as necessary)

Working through these 5 steps may help you develop an informed opinion or critique of a protocol. TRAC is meant to serve as a template or a starting point for discussion. It is encouraged that tribes modify this checklist as necessary to best serve their community in minimizing risks and maximizing benefits of research. Extra space is provided in each of the sections for notes.

TRAC can be used by tribal councils, tribal health directors, tribal health program directors, research administrators, research staff, and anyone tasked with reviewing or conducting research activities in their community.

This may not include all elements which constitute a review by an institutional review board (IRB) as required by federal regulations. TRAC is adapted from the Model Tribal Research Code, Indian Health Service IRB checklist, and the IHS Guidelines for implementing and complying with IHS Policy on specimens.

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**Protocol Title:** \_\_\_\_\_

**PI:** \_\_\_\_\_

**Reviewer:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**STEP I: UNDERSTAND THE RESEARCH AS WRITTEN**

The following questions serve as a guide to understanding the research project. All answers should be readily understandable from the submitted documents and should be explicitly stated in the protocol.

**Research Purpose and Need**

- a. What is the research *type*? (quality assurance, survey, service delivery, clinical trial)
- b. What is the research *question*? What are the goals and objectives of the research?
- c. What do they want to prove or disprove (*hypothesis*)?
- d. What is the *need* for this research as identified in the protocol?

**Data and Data Collection**

- a. What specific kind of information or data are they seeking?
- b. Will the data collected be anonymous?
- c. How will the information be obtained?  
(eg. interviews, surveys, access to previously collected data through a research project, access to individual records such as medical charts, blood or tissue samples, periodic tests conducted throughout project period)
- d. How will the data be maintained? (ie. data security and confidentiality procedures)

**Study Participants**

- a. Who are the participants of this study?  
(eg., adults, children under 18, elders, pregnant women, fetus, people in tribal jail, people with mental impairment, people with a certain health condition)
- b. How will they be identified?  
(eg., tribal enrollment lists, clinic patient lists, student lists, people who belong to a defined group, people who attend a specific event)

**Recruitment and Informed Consent**

- a. How will they be recruited and by whom?  
(eg., phone call, letter, by the primary care doctor during a clinic visit)
- b. Will informed consent be obtained?
- c. What does the consent process entail?
- d. What is the participant compensation?

**Data Analysis**

- a. How will the data be analyzed?
- b. How will individual data be presented? (eg., individual identifying information, individual non-identifying, aggregate information)
- c. How will tribal data be presented? (eg., tribal identifying information, tribal non-identifying, multi-site aggregate information)

**Research Results**

- a. How will the information gained be used?  
(eg., publication, presentation at a conference, develop or enhance tribal health programs)
- b. What will be made of the data at the conclusion of the study?

**STEP II: OBTAIN ALL RELEVANT INFORMATION AND DOCUMENTS**

This step helps to ensure all necessary information and documents are provided according to the research procedures. If additional information is necessary to make an informed decision regarding the study, requests to PIs should be made.

Background and Need		YES	NO	Attachments: ___ Journal articles
Methods and Sampling	N/A	YES	NO	
Recruitment and Consent process	N/A	YES	NO	Attachments: ___ Soliciting advertisement ___ Recruitment letter or information sheet ___ Telephone script ___ Informed consent form ___ Child assent form ___ Parent permission form
Data Collection Method	N/A	YES	NO	Attachments: ___ Data abstraction forms ___ Questionnaire ___ Intake forms
Data Security and Confidentiality Procedures	N/A	YES	NO	
Data Analysis	N/A	YES	NO	
Data Reporting Procedures	N/A	YES	NO	
Documentation of approvals	N/A	YES	NO	Attachments: ___ University IRB (of the PI's affiliation) ___ IHS IRB ___ AATCHB resolution

**STEP III: ASSESS STUDY PROCEDURES**

In this step, actual *judgments* should be made regarding the study procedures. If the research collects specimens, use Step III.X. provided at the end of this document in addition to the following items.

**A. Research Purpose and Need**

- |   |     |     |    |
|---|-----|-----|----|
| 1. Is the research question relevant and appropriate to your community? | N/A | YES | NO |
| 2. Is there a need for this research in your community?                 | N/A | YES | NO |

**B. Data and Data Collection**

- |  |     |     |    |
|--|-----|-----|----|
| 1. Is the information being requested sensitive or private for the <i>individual</i> ? (e.g., sexual behavior, alcohol abuse, child care, etc) | N/A | YES | NO |
| 2. Is the information being collected sensitive or private for the <i>tribe</i> ? (e.g., tribal traditions, tribal values or norms, etc)       | N/A | YES | NO |
| 3. Is the <i>data collection method</i> appropriate for the community? (e.g., the method for collecting specimens is violating tribal values)  | N/A | YES | NO |
| 4. If <i>anonymous for individuals</i> , are data collection procedures adequate to ensure anonymity?  | N/A | YES | NO |
| 5. If <i>confidential for individuals</i> , are data collection procedures adequate to ensure confidentiality?                                 | N/A | YES | NO |
| 6. If <i>confidential for tribes</i> , are data collection procedures adequate to ensure confidentiality?                                      | N/A | YES | NO |

**C. Study Participants**

- |   |     |     |    |
|---|-----|-----|----|
| 1. Are the study participants appropriate for this study? (e.g., researchers propose studying a certain condition in 6-9 year olds, but in your community, it's more prevalent among 9-12 year olds.) | N/A | YES | NO |
|---|-----|-----|----|

*STEP 3 continued***D. Recruitment**

1. Is the recruitment conducted by someone appropriate? (e.g. factors including compensation may influence recruiters to coerce enrollment or someone with a significant status in the community may be coercive)	N/A	YES	NO
2. Does the recruitment letter have all of the relevant information a potential participant would want to know?	N/A	YES	NO
3. Is the recruitment letter written at the appropriate reading level?	N/A	YES	NO
4. Is the participant recruitment process appropriate?	N/A	YES	NO

**E. Informed Consent**

If children under 18 are involved, parental permission and child assent is required. If children are involved, answer E3-8 for parents and complete the child assent section.

1. If the informed consent is waived, is it justified? (if waived, skip to Data Analysis)	N/A	YES	NO
2. If documentation of informed consent is waived, is it justified? (i.e., participants provide verbal consent, but do not sign a form)	N/A	YES	NO
3. Is the informed consent process conducted by someone appropriate? (e.g. factors including compensation may influence recruiters to coerce enrollment or someone with a significant status in the community may be coercive)	N/A	YES	NO
4. Is the method or amount of participant compensation appropriate? (i.e., will not coerce participants, but will adequately compensate them for their involvement)	N/A	YES	NO
5. Does the consent process allow enough time to consider participation and consult with family and others as necessary?	N/A	YES	NO
6. Does the consent form have all relevant information a participant would want to know?	N/A	YES	NO
7. Is the informed consent document written at the appropriate comprehension level?	N/A	YES	NO
8. Is the informed consent process appropriate?	N/A	YES	NO

## STEP 3 continued

9. Child Assent		N/A	YES	NO
a. Is the assent process conducted by someone appropriate?	N/A	YES	NO	
b. Are there criteria for determining when a child does not want to participate?	N/A	YES	NO	
c. Is the method and amount of incentive appropriate?	N/A	YES	NO	
d. Does the assent process allow enough time to consider participation and consult with family?	N/A	YES	NO	
e. Does the assent form have all relevant information a child would want to know?	N/A	YES	NO	
f. Is the assent document written at the appropriate comprehension level?	N/A	YES	NO	
g. Is the assent process appropriate?	N/A	YES	NO	

**F. Data Analysis**

1. If <i>anonymous for individuals</i> , are data analysis procedures adequate to ensure individual anonymity? (e.g., in this tribal community, there will not be many people that will respond yes to this question, so it will make those individuals identifiable)	N/A	YES	NO
2. If <i>anonymous for tribes</i> , are data analysis procedures adequate to ensure individual anonymity?	N/A	YES	NO
3. Is the <i>data analysis process</i> appropriate for community? (e.g., process is not violating tribal traditions or values)	N/A	YES	NO

**G. Research Results**

1. Will researcher obtain review and approval from the tribe prior to dissemination? (publication, presentation, etc)	N/A	YES	NO
2. Will the data be <i>co-controlled</i> by the tribe upon conclusion of the study?	N/A	YES	NO
3. Will the study results be <i>reported back</i> to the tribe?	N/A	YES	NO

**STEP IV: ASSESS RISKS OF RESEARCH**

In this step, actual *judgments* should be made regarding the research risks.

**A. Risks to Individuals**

Will Individuals will be named in the report (Y/N)

1. Participant may be physically harmed by the research	N/A	NO	YES
2. Participants may be emotionally harmed <i>internally</i> (e.g., self-stigmatization, self-guilt, self-doubt)	N/A	NO	YES
3. Participants may be emotionally harmed <i>externally</i> (e.g., personal information made public can result in being discriminated against by others)	N/A	NO	YES
4. Participants may experience “dignitary harms” (e.g., insult to the individual’s respect and control)	N/A	NO	YES
5. Participants may lose tangible “status” (e.g., insurability, discriminated against for jobs)	N/A	NO	YES

**B. Risks to Tribes**

Will the tribe be identified in reports (Y/N)

1. Tribal members as a collective may be physically harmed by the research (e.g., loss of trust in research, loss of trust in services related to research)	N/A	NO	YES
2. Tribe may be psychologically harmed <i>internally</i> (e.g., tribal self-stigmatization, feeling of loss of control or self respect)	N/A	NO	YES
3. Tribe may be psychologically harmed externally (e.g., stigmatization and discrimination by other groups)	N/A	NO	YES
4. Tribe may experience “dignitary harms” (e.g., insult community’s respect and control)	N/A	NO	YES
5. Research could cause disruption of tribal traditions (e.g., tribe’s “private knowledge” could be made public)	N/A	NO	YES
6. Tribe may lose tangible “status” (e.g. loss of political, social, or economic status in larger society)	N/A	NO	YES

**STEP V: ASSESS BENEFITS OF RESEARCH**

In this step, actual *judgments* should be made regarding the research benefits.

**A. Benefits to Individuals**

1. Individuals will learn about their health or health topics in general	N/A	NO	YES
2. Individuals will receive services that otherwise may not be readily available (e.g., diabetes screening)	N/A	NO	YES
3. Individuals will gain emotional benefits (e.g., self-respect, self-esteem, pride of resiliency)	N/A	NO	YES

**B. Benefits to Tribe**

1. Information collected will be something that the tribe can use (e.g., to improve their programs)	N/A	NO	YES
2. Information collected may lead to additional funding in the near future	N/A	NO	YES
3. Project will provide local tribal staff or tribal college students with training (e.g., on health topics, interviewing methods, data collection and entry, research ethics, etc)	N/A	NO	YES
4. Project will employ local tribal staff or tribal college students (e.g., as coordinator, data collectors, data entry staff, etc.)	N/A	NO	YES
5. Project will provide tribe with equipment (e.g., computer)	N/A	NO	YES
6. Project will help mobilize the community (e.g., in the process create working groups, obtain community buy-in)	N/A	NO	YES
6. Tribe will gain psychological benefits (e.g., community pride)	N/A	NO	YES

**C. Benefits to society as a whole**

1. Information collected will be useful to other tribal communities	N/A	NO	YES
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**STEP III.X. ASSESS STUDY PROCEDURES FOR RESEARCH INVOLVING SPECIMENS**

In this step, actual *judgments* should be made regarding use of specimens.

1. Does the specimen collection process violate or conflict with cultural values?	N/A	NO	YES
2. Will the procedures to store specimens for use during this project period violate or conflict with cultural values? (e.g., location and duration)	N/A	NO	YES
3. Will the specimen analysis process violate or conflict with cultural values?	N/A	NO	YES
4. Will the procedures to dispose of the collected specimens violate or conflict with cultural values?	N/A	NO	YES
5. Will the specimen will be stored for future “secondary” studies? If yes:	N/A	NO	
a. Is the nature of the proposed secondary use described adequately in the protocol and consent form?	N/A	NO	YES
b. Is the nature of the proposed secondary use appropriate for the community?	N/A	NO	YES
c. Will the procedures to store specimens violate or conflict with cultural values? (e.g., location and duration)	N/A	NO	YES
d. Will the procedures to dispose of the specimens violate or conflict with cultural values? (e.g., location and duration)	N/A	NO	YES
e. Is there adequate assurance that the researchers (and all other with potential access) will comply with all necessary procedures to conduct a secondary study? (e.g., requirements can differ whether the secondary use is related to the original study, but may include providing full protocol for review to all relevant tribal and institutional entities and seeking formal approval prior to use)	N/A	NO	YES
i. Are there signed written agreements from all relevant research personnel?	N/A	NO	YES
ii. Are there signed written agreements between the researchers and institutions to define responsibility over the storage and disposal of specimens in the case the PI leaves the institution (i.e., “institutional memory”)	N/A	NO	YES
f. If specimens are “nonrenewable,” are there adequate steps to ensure the scientific value of the proposed secondary use? (i.e., the protocol must include procedures for an independent group to assess the scientific value of the proposed secondary use of nonrenewable specimens. Nonrenewable specimens should be used up only by research with high scientific value. Specimens also must not be hoarded, but must be shared if it benefits the individual or tribal community. These criteria are especially important for specimens not easily obtained, such as by surgery or biopsy.)	N/A	NO	YES
g. If specimens are “nonrenewable,” are the proposed secondary uses of high tribal importance?	N/A	NO	YES