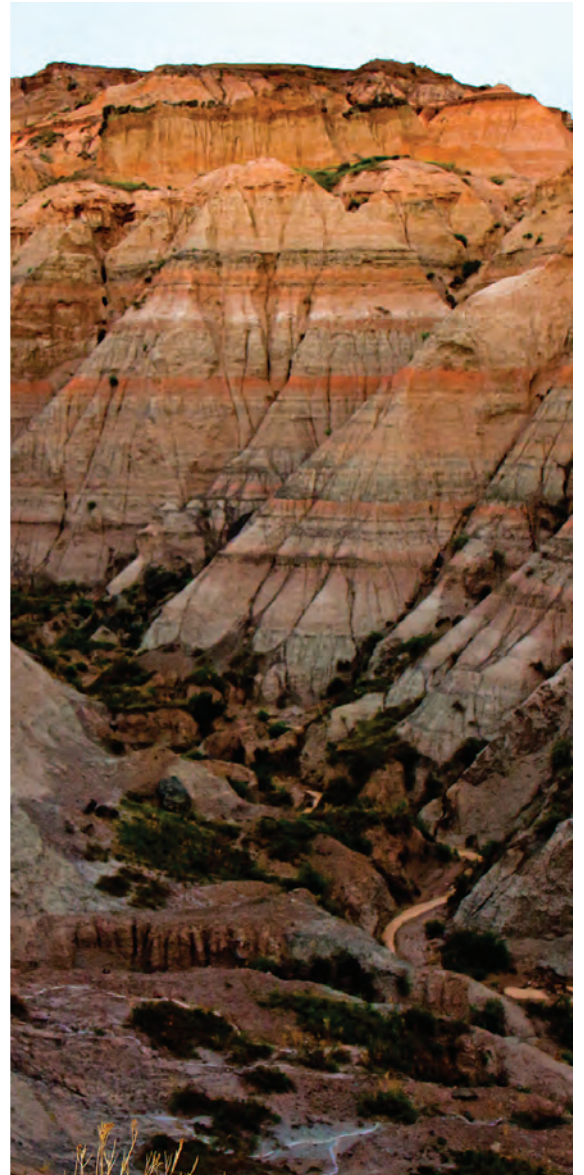




Collaborative Research Center for American Indian Health Tribal IRB Toolkit



Project is supported by the National Institute on Minority Health and Health Disparities of the National Institutes of Health under Award Number U54MD008164.

This toolkit is intended to serve as a resource for American Indian Tribal Nations or other Indigenous Nations developing Institutional Review Boards (IRBs) or other committees responsible for ethical review and monitoring of research on Tribal land. The CRCAIH IRB toolkit was developed by the Collaborative Research Center for American Indian Health (CRCAIH), Regulatory Knowledge Core, in response to specific requests and inquiries from CRCAIH Tribal partners and offers practical tools and guidance necessary to start an institutional or a research review board. This Toolkit is available to the public free of charge at www.crcaih.org.

The Collaborative Research Center for American Indian Health (CRCAIH) brings together tribal communities and health researchers within SD, ND, and MN. Our goal is to build tribal research infrastructure and transdisciplinary research teams to improve American Indian health through examination of social and environmental influences on health.

Based on Tribal IRB requests, we expect to develop additional resources and training tools for the web version of the CRCAIH TRIBAL IRB toolkit. We are grateful to our CRCAIH Tribal Partners for providing feedback and recommendations to enhance the utility of the tools provided in this resource.

Correspondence, including questions and requests should be directed to:
Jyoti Angal MPH, CIP
Director, Regulatory Knowledge Core
Sanford Research, Center for Health Outcomes and Prevention Research
Collaborative Research Center for American Indian Health
jyoti.angal@sanfordhealth.org

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WHY ESTABLISH A TRIBAL IRB?

What is an IRB?

An Institutional Review Board (IRB) is responsible for the ethical review and oversight of research for the protection of human subjects.

What is a tribal IRB?

A tribal IRB often assumes responsibility for the ethical review and oversight of all research occurring on tribal land; which includes the protection of human subjects, the Tribe, tribal communities, and tribal resources (including environmental, animal, plant and cultural resources).

Benefits of a tribal IRB

- Allows for greater and more consistent research protections for the community
- Allows for the incorporation of Tribe-specific values to policy regulating research
- Creates clear guidelines and contracts for collaborations between researchers and the Tribe, making the research review process more efficient
- Effectively prevents research related harms to individuals and the community as a whole, and ensures Tribes benefit from research conducted on Tribal land
- Facilitates the development of Tribal researchers and tribally based research projects
- Facilitates the cataloging of evidence-based information (from the record-keeping of research and research data) that can be useful for grant-writing and policy development

References

Deloria, Philip S. The Role of Tribal Government in Regulating Research. Northwest Portland Area Indian Health Service Institutional Review Board, 2003. http://www.npaihb.org/images/epicenter_docs/irb/docs/deloria_fr.pdf

Morton, D. J., Proudfit, J., Calac, D., Portillo, M., Lofton-Fitzsimmons, G., Molina, T., Majel-McCauley, R. (2013). Creating research capacity through a tribally based institutional review board. *Am J Public Health*, 103(12), 2160-2164. doi: 10.2105/ajph.2013.301473



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How to use the CRCAIH IRB Toolkit

The Tribal IRB Toolkit contains tools and tips for starting a tribal IRB. It is recommended that on first read, users explore all components of the Toolkit in alphabetical order, A-E. Thereafter the toolkit can be used as an educational tool, and process tool. In the electronic version of the toolkit all files and subfolders are listed in numerical order. We provide many template documents in Microsoft Word format to facilitate use and customization of these resources by tribes and communities, free of permissions. We only ask that you acknowledge the source when appropriate!



STARTING A TRIBAL IRB

1. Obtaining Tribal IRB Approval
2. Naming Your Tribal IRB
3. Developing Policies and Procedures
4. Selection and Recruitment of IRB Members
5. Orientation and Training of IRB Members

OBTAINING TRIBAL APPROVAL

A systematic research review process ensures responsible conduct of research, community ownership of research review process and the most comprehensive level of human subjects protections. Increasingly, Tribal Nations are establishing tribal IRBs to self-regulate research. However, setting up Tribal IRB needs considerable forethought and planning. Tribal government approval and support is essential for the formation and sustainability of a tribal IRB. This process, including the length of time necessary for the approvals may differ from one Tribal Nation to another.

Tribal Resolution, Ordinance and Research Code

Tribes may authorize establishment of an institutional review board through an Ordinance, Resolution or Research Code. While a community member or a group can lead the initiative on establishing a review board, we recommend that legal guidance and input should be sought from a lawyer who works for the Tribe to ensure compliance with Tribal laws and processes. Critical issues such as authority and functions of the IRB, process for overseeing IRB functioning, and mechanism to address violations of the research codes should be included. Developed by the American Indian Law Center, the [Model Tribal Research Code](#), is available to the public via the Indian Health Service (IHS) website. Tribes may use this as a template for developing their individual codes.



NAMING YOUR TRIBAL IRB

[FREQUENTLY ASKED QUESTIONS]

Q1. Is 'IRB' the name for academic and/or medical institutions and a Research Review Board (RRB), the name for a Tribe or community?

Answer: No. 'IRB' is a generic term used by Food and Drug Administration (FDA) and Health and Human Services (HHS) to refer to a group whose function is to review research to assure the protection of the rights and welfare of the human subjects. Each institution may use whatever name it chooses." (U.S. Food and Drug Administration, Institutional Review Boards Frequently Asked Questions – Information Sheet. Guidance for Institutional Review Boards and Clinical Investigators.)

Q2. Can Tribal Nations reviewing research have a name that does not use the words "Review" or "Board"?

Answer: Yes. The board can be assigned any name. The words "Review" and "Board" are not required (personal communication, Dr. Harold Blatt, Assurances/IRB Registrations, Office for Human Research Protections (OHRP), June 2, 2014).

Q3. We have a board and it is not registered with the Office for Human Research Protections (OHRP) – can we call it an IRB?

Answer: Yes. Boards that are not registered with the Office for Human Research Protections (OHRP) can have the name IRB.

Q4. If we register our Tribal board with the Office for Human Research Protections (OHRP), will we need to change our name to IRB?

Answer: No. In the OHRP [database](#), the board is listed as an 'IRB' and assigned an 'IRB number', irrespective of the board's actual name (personal communication, Dr. Harold Blatt, Assurances/IRB Registrations, Office for Human Research Protection (OHRP), June 2, 2014).

Sources

Blatt, Harold. Assurances/IRB Registrations, Office for Human Research Protections (June 2, 2014) Telephone communication.

U.S. Food and Drug Administration, Institutional Review Boards Frequently Asked Questions – Information Sheet. Guidance for Institutional Review Boards and Clinical Investigators. Accessed July 23, 2014 at <http://www.fda.gov/regulatoryinformation/guidances/ucm126420.htm>



DEVELOPING POLICIES AND PROCEDURES

- 1. Tribal IRB Policy and Procedure
Development Guide**
- 2. FAQs on IRB Fees**
- 3. IRB Registration and FWA**

TRIBAL IRB POLICY AND PROCEDURE DEVELOPMENT GUIDE

A. INTRODUCTION

A1. Purpose, Scope, and Mission of Board

- Why an institutional/research review board?
- Reference to legal documents (e.g. Resolution, Act or Code, Federal Wide Assurance)
- The purpose the board will serve for the Tribal Nation
- Applicable tribal laws, standards and values, as well as state, national and international (e.g. Tribal Nation standards/values, U.S. standards, international standards. For more details, please see section on 'recommended resources'.

A2. Purpose and Applicability of Policies and Procedures

- Broad description of document contents (e.g. 'This document contains..')
- Who must abide by these policies and procedures? (e.g. researchers, tribal IRB members)
- Relationship of policies and procedures to tribal law
- Statement about revision of the document (e.g. 'This document will be reviewed annually and updated as deemed necessary to reflect new tribal, national, and/or international standards in human subjects research protections and community protections in research.')
- Pertinent definitions (research, human subject, minimal risk)

A3. Roles and Responsibilities

A3.1 *IRB/RRB Scope of Authority & Responsibility*

- Itemize what will fall under the board's authority for review or monitoring (e.g. human subjects research, economic research, environmental research, cultural research, historical research)
- List the responsibilities the board will assume

A3.2 *Health Committee Authority & Responsibility*

(Or other relevant department or tribal institution/organization whose responsibility overlaps with that of the board, or under whose authority or overhead the board operates)

A3.3 *Principal Investigator/Researcher Authority & Responsibility*

- Overview of the requirements of researchers wishing to conduct research on tribal land

- Should researchers be available to the board at meetings when their research is being reviewed? If yes, how should they be available? (e.g. email, telephone, video conference, in person)
- ‘Researchers must report all proposed changes in a research activity to the institutional/research review board and said changes may not be initiated without review and approval.’
- ‘Researchers must report any unanticipated problems involving risks to participants or others, or any non-compliance with the policies of the institutional/research review board.’
- Researchers may not start research involving human subjects/participants, even in a medical emergency without prior institutional/research review board approval
- Researchers must only distribute informed consent forms with current IRB approval dates on them
- Statement about research responsibility to share results of their research with the Tribe, how and when they should do so [e.g. preliminary and final results of research in a lay-man’s summary including a)summary of work done, b) why it was done, and c) the potential value of the results]

B. COMPOSITION AND APPOINTMENT OF IRB/RRB

B1. Member Types and Responsibilities

- Guidelines for board membership, how many members, expertise of members, gender, affiliations, representation (e.g. Tribes may elect to have representation from specific districts or communities or from specific departments/organizations within the Tribe)
- Description of roles and responsibilities within board membership (e.g. chair, coordinator, secretary, treasurer)
- Decide if there will be both ‘primary members’ and ‘alternate members’ who can replace ‘primary members’ when they are unable to make a meeting e.g. Guidelines provided by the Office for Human Research Protections (OHRP), 45 CFR 46.107 IRB
Membership:<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.107> In brief:
 - a) At least 5 members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB should be sufficiently qualified through the experience and expertise of its members, the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to

such issues as community attitudes, to promote respect for is advice and counsel.*The IRB should be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, and applicable law.

- b) Will not consist of entirely men or entirely of women; will not consist of individuals entirely of one profession.
- c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. **
- e) No member may have a member participate in the initial or continuing review of any project in which the member has conflicting interest
- f) If the IRB invites an external consultant to assist with review of a particular research study, that individual may not vote with the IRB.

*Many tribal IRBs elect to have board members be all individuals who reside on the reservation. In this case diversity of race and culture can be understood within that existing on the reservation.

**Item (d) is to insure impartiality with regards to the interests of the 'institution'. If abiding by OHRP membership guidelines, the tribal IRB must determine how it will interpret 'institution' and write this in the Policy and Procedure document. A recommendation by Dr. William Freeman in his 2007 publication, *Starting an Institutional Review Board (IRB): Suggestions for Tribes, Tribal Colleges, and Communities*; is to interpret 'institution' to mean Tribal government. He recommends that each tribal IRB consist of one member who is not employed by the Tribe, nor has immediate family employed by the Tribe. If the IRB is being run out of a department or organization within the Tribe, example the college or health department, 'institution' could also refer to that institution or department.

B2. Appointment or Election of Members

- Description of process whereby individuals are granted membership on the board
- Will they be appointed or elected? If either, how?
- Will there be recruitment of individuals? Will the opportunity to serve be publicly posted?

B3. Terms of Membership & Commitment

- What is an individual's commitment of time as member of the board? (monthly, yearly)
- Describe what individuals commit to doing, in service as members of the board?
- Is there an attendance policy?
- Are there options for attendance? (in person, video conference, telephone)
- Must members serve for a specific length of time?

- A 'letter of commitment' outlining the terms of membership for individuals to sign

B4. IRB Member Training

- Description of how individuals serving on the board will be trained for their role

B5. Member Resignation

- Description of process by which a board member will be asked to resign (e.g. outline the types of behavior that will lead to a resignation)
- Description of process by which a board member can elect to resign
- Who will make the final decision regarding resignation of board members? (including specific members such as chair)
- What is the time frame in which a resignation should be submitted? (Consider the time needed to find a replacement for individual resigning.)

C. IRB/RRB Review Process

C1. Overview of the review process

C1.1 General Description

- Include statement describing submission deadline system or other system for placement on board meeting agendas
- How will it be determined if an activity falls within the board's jurisdiction for review? Who will be responsible for making that determination?
- Describe the system of review. Will there be a 'primary reviewer' system, i.e. will individual protocols be assigned to 1 or 2 board members for in depth review to reduce the burden of review for each member? Will all board members be required to perform an in depth review of every protocol?
- Provide a time window in which documents will be distributed to board members prior to meetings (e.g. 1 week, 2 weeks)
- Describe how board 'actions' or decisions, requests, and other correspondence with researchers will occur
- Description of what is required for board approval of research (e.g. no more than minimal risk to the participants and to the community, maximized benefits to the Tribe, no coercion, voluntary participation, fully informed consent, permissions from appropriate departments within the Tribe.

C1.2 Confidentiality

- Outline policy regarding board member disclosure of information, activities/research projects reviewed in the course of service on the board

C1.3 IRB member Conflict of Interest

- Board members are responsible for disclosing conflict of interest prior to participating in the review of research
- Describe the terms under which a board member may not be allowed to review research because they will not be able to remain impartial.
- ‘Conflict of interest’ refers to situations where financial or other personal considerations may compromise or appear to compromise a board member’s professional judgment or objectivity in reviewing a research project.
- Determine if ‘conflict of interest’ includes financial and/or personal interests of board member and specific family members (e.g. spouse and children)
- Board members should remove themselves from the meeting room when research is being reviewed for which they have a conflict of interest, and their absence and reason for absence should be noted in the meeting minutes.

C1.4 Policy regarding Undue Influence on IRB

- Describe the board’s goal with respect to objective and impartial review and action
- Describe institutional/research review board policy regarding pressure or gifts to favor or disfavor specific research projects, researchers, or institution

C2. Meetings

C2.1 Frequency, Agenda, Scheduling

- How often will meetings be held? Who will schedule them? (‘As needed’ meetings are also an option for boards without a constant flow of research protocols to review)
- Who will be responsible for preparing and distributing meeting agendas and materials for meetings
- How will research projects be placed on a meeting agenda? In order of submission? Items from previous meeting first? Where will new initial reviews and continuations fall?
- Will meetings run for a pre-determined length of time? Or will meetings run until every item on an agenda has been reviewed?

C2.2 Quorum

- State when quorum is required (e.g. for full board review as opposed to ‘expedited review’)
- State how many individuals must be present in order to make quorum. (Office of Human Research Protections requires one more than half the number of primary board members.)

- Consider whether or not there is existing tribal policy regarding board meetings
- Write a statement regarding non-board members at meetings (ex. consultants, researchers, community members, and other interested individuals). Will meetings be 'open' or 'closed', or 'open to guests with permissions'?

C2.3 *Minutes*

- When will minutes be taken? (recommended they be taken at every meeting)
- Describe required elements of meeting minutes
The Office for Human Research Protections recommends that minutes include: i) actions and votes for each protocol undergoing review, ii) votes on all board actions, including the number voting for, against, and abstaining, iii) rationale for changes requested of the researcher by the board, iv) documentation of the continual existence of a quorum
- Who will have access to meeting minutes?

C3. **Initial Review: Convened IRB (full board review)**

- Write description of what 'full board review' means
- Describe how the review will take place
- Write a short list of institutional/research review board 'action' terms and definitions (e.g. 'approve', 'abstain', 'disapprove', 'table', 'suspend')
- Include statement that includes the following: 'The institutional/research review board requires prompt reporting of proposed changes to an approved research activity. Changes may not be initiated without board review and approval, except when necessary to eliminate immediate hazards to the participants or others.'
- List the documents that will be provided to reviewers for full review (e.g. initial review application form and accompanying documents including research protocol, consent form, and any recruitment materials, or grant applications - if applicable)

C3.1. *Full Board Review Protocol Approval Process*

- Describe approval process, including the minimum required for approval to be granted, and the number of votes required for an approval. Include the term selected to describe this type of board 'action' (e.g. a protocol is 'approved' when a majority of the quorum votes 'approve', or in favor of granting permission for the research to be conducted)
- If there is to be approval with contingencies, or approval granted on a condition that the researcher complete certain requests made by the board, describe the

process. Include the term to describe this type of board 'action'. E.g. 'conditional approval', 'contingent approval'

- Describe form of approval communication to researcher (e.g. approval letter, dates of IRB approval on information consent documentation, recruitment flyers)

C3.2 Full Board Review Requesting Revisions from Investigators and 'Tabling' Review

- What will be the format for communication with investigators regarding requests for revisions or additions to projects submitted for review
- Describe the process for postponing review. An optional board determination term that can be used is 'table'
- Include rationale for postponing review and how this will be communicated to relevant researcher(s)
- How will projects be placed on a future board meeting agenda?

C3.3 Full Board Review Process for Denying Approval

- Describe the rationale and process for denying approval. Include the board determination term that will be used (e.g. 'deny', 'disapprove')
- Describe the voting process for this board determination (e.g. denial of approval requires a 'disapprove' vote from the majority of quorum)
- Include description of an appeal process, if researchers will be given the option to appeal a decision made by the board.

C3.4 Full Review Process for review of amendments to protocols, unanticipated and adverse events

- Describe review process for each of these items. Which will be full review? Which will be expedited review? Which will require a specific type of review system?
- Amendments to protocols and informed consent documents should be submitted within the entire protocol document and can be denoted with different color ink, track changes or highlighting.

C4. Initial Review: Expedited Review

- Determine if there will be an 'expedited review process', a review process generally conducted by only one or a few members of the board and resulting in one of the following 'determinations' - approval, revisions required or sent to full board review. Protocols cannot be disapproved by an expedited review.

- Who will designate the individual(s) to conduct ‘expedited review’ or will it always be the same individual? (e.g. chair or coordinator, a particular board member)
- Which items will routinely undergo expedited review? (E.g. poster presentations, certain types of amendments, manuscripts, and ‘letters of support’ for grant proposals.) The categories for expedited review listed by the Office for Human Research Protections can also be included:
<http://www.hhs.gov/ohrp/policy/expedited98.html>
- What must be submitted with each of these items to undergo expedited review? (e.g. layman’s summary, specific statements to be included in ‘letters of support’)
- Describe how the ‘determinations’ or decisions resulting from an expedited review will be communicated to the rest of the board (all members).

C4.1 Expedited Review Protocol Approval Process

- Describe the process, number of votes
- Describe approval communication to researcher (e.g. approval letter, dates of IRB approval on information consent documentation, recruitment flyers)

C4.2 Expedited Review, Requests for Revisions, “Tabling” Process, Process of Moving to “Full Review”

- Describe process(es) whereby individual(s) conducting expedited review may request more information from a researcher, postpone review, or require that the research study move to a “full review” process involving all the members of the board.

C4.3 Expedited Review Process for Denying Approval

- Describe process, number of votes

C5. Continuing Review: Full Review

- Describe how often continuation or renewal approval must be granted (Office for Human Research Protections requires that while a research study remains active, it be reviewed a least one time per year, before the anniversary of the date of initial approval. The board also has the option to require more frequent review on a case by case basis. If board decides to review more frequently than one year, detailed criteria for making that determination must be included.)
- Describe procedures that the board will follow should it need to obtain information from a source, other than the research investigator, regarding changes to the protocol since the previous approval (e.g. for projects that are

high risk or complex, for projects conducted by investigators with history of non-compliance)

- List the documents that will be provided to reviewers for full review (e.g. continuation/renewal application form and/or progress report on the research project, and accompanying documents including an amendment form, if applicable, and any documents on which changes are being proposed, such as protocol, consent, and recruitment materials)
- Include statement that 'continuing review' will be scheduled such that there will be time for the IRB to review the research project and communicate a decision to the relevant researcher, prior to the expiration date of the current institutional/research review board approval

C5.1. Continuation Review Approval Process

- Describe approval process, including the minimum required for approval to be granted, and the number of votes required for an approval.
- Describe approval communication to researcher (e.g. approval letter, dates of IRB approval on information consent documentation, recruitment flyers)

C5.2. Continuation Review Process for Requesting Revisions from Investigators and 'Tabling' Review

- What will be the format for communication with investigators regarding requests for revisions or additions to research projects submitted for review?
- Describe the process for postponing or 'tabling' review. Describe when research projects will be allowed to continue while tabled and awaiting continuation approval, or under what circumstances they will have to halt.
- Include sample rationale for postponing review and how this will be communicated to relevant researcher/s
- How will projects be placed on a future board meeting agenda?

C5.3 Continuation Review Process for denying continuation of a research project

- Describe sample rationale for denying continuation of a research project, number and type of votes
- Include description of an appeal process, if researchers will be given the option to appeal a decision made by the board.

C6. Continuing Review: Expedited Review

- Describe when an expedited continuation review may be applicable

- According to the Office for Human Research Protections, an ‘expedited review’ is generally not appropriate for continuation review if initial review or previous review was a ‘full review’
- The specific categories for expedited review listed by the Office for Human Research Protections: <http://www.hhs.gov/ohrp/policy/expedited98.html>

C6.1. Expedited Review Protocol Approval Process

- Describe the rationale for granting continuation and the process, including the number of votes

C6.2 Expedited Review Requests for Revisions, “Tabling” Process, Process of Moving to “Full Review”

- Describe process(es) whereby individual(s) conducting expedited review may request more information from a researcher, postpone review, or require that the research study move to a “full review” process.

C6.3. Expedited Review Process for Denying Approval

- Describe process, number of votes and reasons whereby a research project may be denied continuation
- Include description of an appeal process, if researchers will be given the option to appeal a decision made by the board.

C7. Review of Completed research project/ Project ended prior to completion

- Describe review of project termination/completion report from researcher
- Describe the board’s processes for ensuring that data and results from the projects, including publications, are returned
- Include language about the board’s right to request additional information from investigators

C8. Review of Research Products

- Describe which (if any) products will be under the boards jurisdiction for review (e.g. manuscripts, oral and poster presentations)
- Detail the review process and the possible board ‘determinations’ upon review; or refer to an applicable review process already described in the document (e.g. initial review-full review or initial review- expedited review)

D. RELATED TO SPECIFIC TYPES OF RESEARCH

This section is optional and can be included in this document as the need arises, and depending on the type of research commonly conducted on tribal land.

D1. Research in Educational Institutions

D2. Vulnerable Populations (pregnant women, human fetuses or neonates; prisoners; children)

D3. Research using Biospecimens and/or Biospecimen repositories

D4. Investigational Drugs

D5. Internet Research

D6. Research using Deceptive Disclosure or Incomplete Disclosure

D7. Research using Genetic Materials

D8. Health Record Research

D9. Research with Secondary Data

D10. Environmental Research

E. IRB/RRB RECORD KEEPING

- List of records to be retained, length of time, and policy around security and access to records (Office for Human Research Protections according to 45 CFR46.115, requires that registered institutional review boards keep records of the following for a minimum of 3 years after completion of a research study):
 - all research proposals reviewed,
 - approved sample consent documents,
 - progress reports,
 - unanticipated problem and incident reports,
 - continuation approvals,
 - board meeting minutes,
 - correspondence between the board and investigators,
 - a roster of IRB members,
 - all versions of policies and procedures for the board,
 - Record-keeping specific to fee billing and collection

F. GUIDELINES FOR INVESTIGATORS SUBMITTING MATERIALS FOR REVIEW

- Itemize investigators submission requirements for each type of submission (e.g. initial review, continuation, amendments, publications and presentations, project termination or completions reports), or refer to specific submission forms to be completed, or external document outlining this information

G. FEE SCHEDULE

- Determine if there will be initial review fees, continuing review fees, fees process for studies with components parts, fees for IRB comment and review, fee waivers, student fees
- A fee table is often an easy to understand format (including items for which there is no charge)

H. REPORTING REQUIREMENTS AND PROCEDURES

H1. Investigator Reporting Requirements

- Itemize what researchers must report to the board and how (e.g., changes to protocol, unanticipated events, adverse events, participant complaints, study completion or discontinuation, publication)

H2. IRB/RRB Reporting Requirements and Procedures

- Outline what departments, institutions, agencies the board must report to. Include what must be reported, (e.g. report of IRB activity, actions) how it will be reported, and when, or how often (e.g. Health Committee, Tribal Council, Office for Human Research Protections)
- The board must report items like unanticipated problems involving risk to subjects and others, serious or continuing non-compliance, 'suspension' or 'termination' of institutional/research review board approval. Include the time frame required for the reporting of these items.
- If applicable, include a description of a process for further review and approval (e.g. Tribal Council approval following board approval)



FAQs on IRB FEES

IRB FEES: FAQs FOR TRIBAL INSTITUTIONAL REVIEW BOARDS

Q1. Should Tribal IRBs Charge Fees?

Obtaining key information about research currently being done on your reservation such as the quantity, type, and sources of research will help inform decision making:

- Approximately how many research proposals does your board review or is expected to review in a year?
- Who is leading the majority of the research projects? (e.g. departments within the Tribe, external academic institutions, medical institutions, commercial agencies, student researchers)
- What are the primary funding sources for the research applications submitted for review?
- Estimate operational costs for your IRB. IRB fees can help offset some of the operational costs (e.g. space, personnel and other resources for IRB coordination activities such as printing, storage of research protocols compensation for reviewers)

Q2. Is there information on fees charged by other American Indian (AI) Tribal IRBs?

Only a handful IRB have made their fee information public available fee information for the following Tribal IRB's is available online:

- Southwest Tribal IRB has fee information written into their IRB policies and procedures:
http://www.mynarch.net/uploads/FileLinks/723a189f14d14629b1a2eedd83e45034/REV_SW_Tribal_IRB_policies_Feb_2014.pdf
- Fort Peck IRB has fee information available on their website:
<http://www.fpcc.edu/irb-home.php>

Many academic medical centers (AMCs) and universities charge a fee and make their IRB fee schedules publicly available on the internet.

- Unpublished surveys conducted in 2000 indicated that AMC IRBs charged between \$500 and \$2,000 for initial review, with an average fee of \$1, 130. (Amdur & Bankert 2005)
- IRB fee process should be designed to encourage research and not deter research.

Q3. Should there be a policy for billing and collection of IRB fees?

Developing a system and written policy for how fees will be billed and collected including handling of late payment of fees; is essential and should be a part of the IRB policies and procedures. (Amdur and Bankert 2005). Some institutions collect up front, prior to review; others collect prior to final approval decision is granted (Amdur and Bankert 2005).

Q4. Should IRBs charge for ‘initial review’, ‘continuing reviews’, and ‘amendment review’?

- Generally the initial review fee is the highest fee charged by institutional review boards
- Some institutions only charge for initial review; others charge for continuing review and amendments as well. (Amdur & Bankert 2005)
- IRBs may consider charging a lower fee for studies in which enrollment has been completed and only data analysis remains.

Q5. Can research investigators use grant funds for IRB fees?

For National Institutes of Health (NIH) funded studies, institutions cannot charge costs associated with IRB review as direct costs. Costs associated with IRB Review should be covered by indirect costs (institution’s facilities and administrative rate). For more information please see [NIH Grants Policy Statement](#).

Q6. Should there be waivers or reductions of review fees?

Waivers or fee reductions could be granted in certain types of research:

- Studies with limited funding
- Student research
- Tribal investigator initiated research
- Research requested by Tribe

References

Amdur, R. Bankert, E. (2005). Institutional Review Board Management and Function. Second Edition.



IRB REGISTRATION & FWA

SHOULD A TRIBAL IRB GET AN FWA

[FREQUENTLY ASKED QUESTIONS]

Q1. What is a Federal Wide Assurance?

A Federal Wide Assurance (FWA) is document that an institution submits to the Office of Human Research Protections (OHRP). It is a written commitment to comply with the federal regulations for the protection of human subjects. Currently the FWA is the only type of assurance accepted by OHRP.

Q2. Why obtain an FWA?

An FWA makes an institution eligible to apply for, and be a direct recipient of federal funding for human subjects research. It is required for institutions that are in 'engaged'* in (non-exempt*) research involving human participants - that is conducted or supported by the U.S. Department of Health and Human Services.

Q3. How does FWA affect tribal laws governing research?

Having an FWA means that the Tribe is agreeing to comply with and enforce federal human subjects' protections regulations as a minimum. Tribes and all institutions that choose to obtain an FWA have the right to establish regulations in addition to the existing federal regulations protecting human subjects. For example, Tribes can incorporate federal human subjects' protections regulations into their own policy regarding research conducted on Tribal land.

Q4. Can a tribe be an 'institution' as defined by the Office for Human Subjects Protections?

Yes. Tribes are often treated as "public entities" or referred to as "tribal entities".* For those who consider a Tribe or Tribal department to be a non-U.S. institution, the OHRP guidelines regarding non-U.S. institutions are as follows: "...Whenever non-U.S. institutions are engaged in non-exempt HHS-supported or -conducted human subjects research, the regulations apply."**

Q5. Does an institution applying for an FWA need to have its own IRB?

No. An institution can list an external IRB registered with OHRP (and their IRB registration number) on its FWA application. However, both organizations must be agree on this relationship, and confirm the relationship to OHRP with a written 'IRB authorization agreement' (see CRCAIH Glossary) between institutions.

Q6. Our tribe does not have an IRB. What are our options?

Tribes that do not have an IRB can apply for an FWA. Tribes have the option of establishing an IRB authorization agreement in one of the following ways:

- With another Tribe that has an IRB
- With a local Tribal Consortium IRB
- With regional IHS IRB, Tribal College IRB or other institutional IRB

Q7. What is the connection between obtaining an FWA and 'registering your IRB'?

These are two separate processes. However, in order to obtain an FWA, an 'institution' must designate a 'registered' IRB that is designated for the review of research for that institution. An institution may either 'register' its own IRB or list another institution's registered IRB, and submit a formal IRB authorization agreement to OHRP.

Q8. Why register an IRB?

- A 'registered' IRB can be listed on an institution's Federal Wide Assurance (FWA) application.
- An institution that registers its own IRB can keep the review of research "in house"
- Registration can also be a way to demonstrate that an institution's IRB operates in accordance with established federal standards.

Q9. How does registering your IRB work?

IRBs have the option to apply for 'registration' with the U.S. Department of Health and Human Services (HHS), Office of Human Research Protections (OHRP). Upon registration:

- The IRB and hosting institution, which is referred to as 'IORG' by OHRP, will be placed in an OHRP database
- The institution and designated IRB will be assigned an IRB number and an IORG number respectively. These numbers are accessible to the public and can be listed in grant applications and grant correspondence.
- A registered IRB is subject to audits from OHRP

Q10. What are the prerequisites for IRB registration?

Before you begin your registration process, you should have the following information at hand:

- Identify number of active research protocols (or research studies 'current' or 'in process') in the past year.
- Identify number of active research protocols conducted or supported by the U.S. Department of Health and Human Services (HHS).
- The contact information for the following:
 - the institution
 - a top institutional or Tribal official
 - IRB Chairperson
 - designated contact person for the IRB
- A roster of the IRB membership and each individual's role on the IRB - in accordance with federal guidelines
- For other requirements, access the electronic application here:
<http://ohrp.cit.nih.gov/efile/Default.aspx>

*For further information on 'engagement of institutions', and 'non-exempt', see the terms 'engagement' and 'exempt' in the [CRCAIH Glossary of Human Subjects Protections Terms](#).

Reference:

Federal Wide Assurance for the Protection of Human Subjects 3(c). Accessed July 17, 2014:
www.hhs.gov/ohrp/assurances/assurances/filasurt.html#sectionb



SELECTION AND RECRUITMENT OF IRB MEMBERS

- 1. Tribal IRB Organization**
- 2. IRB Member Selection Guidelines**
- 3. Sample Recruitment Advertisement**
- 4. IRB Member Letter of
Commitment**

TRIBAL IRB ORGANIZATION

An Institutional Review Board (IRB) is comprised of IRB members and a Chair. They are all typically voluntary positions supported by the paid position/s of an administrative IRB person or persons (e.g. IRB coordinator).

BOARD COMPOSITION

IRB Chair

The Chair directs the convened or full board IRB meetings. The extent of the role of the Chair is optional. A Tribal institution or Tribe may choose to have the Chair vote at a meeting or serve as a non-voting member. An IRB Chair may only direct the full committee IRB meeting. An IRB Chair may also play a leadership role in establishing and implementing IRB policy, serve as an expert on local, state, and federal regulations related to research ethics and human subjects protections in research, and serve by conducting expedited reviews*.

IRB Members

IRB members serve in the review of research for the board. They contribute their individual areas of expertise and perspectives to a team effort for the ethical review of research.

ESSENTIAL SUPPORT POSITIONS

IRB Coordinator

The IRB Coordinator is an administrative role responsible for coordination, preparation, and communication before, during, and after board meetings. The coordinator may also be selected to represent the board to external organizations and individuals.

IRB Institutional Official

The IRB is also supported by the role of an Institutional Official (IO), a high ranking outside the board. This may be the head of a Tribal department or institution that has been charged with supporting the Tribal IRB (e.g. Health Administrator, Tribal College President), or may be a Tribal government official.

This individual is responsible to the Office of Human Research Protections for ensuring the board's compliance with federal human subjects' protections regulations. This 'responsibility' to the Office of Human Research Protections is particularly relevant if the Tribal institution or Tribe acquires a Federal Wide Assurance (FWA)*. The Institutional Official (IO) oversees and supports the administrative operation of the IRB. The IO can also serve as a mediator if serious problems arise that cannot be resolved within the board.

*For more information on these terms, please utilize the [CRCAIH Glossary of Human Subjects Protections Terms](#) which contains definitions and resource links. It is also included in the reference section of this Tribal IRB Toolkit.

References

Bankurt, Elizabeth A and Amdur, Robert J. 2006 Institutional Review Board Management and Function Second Edition. Burlington MA: Jones & Bartlett Learning.

IRB MEMBER SELECTION

IRB members may be nominated or selected through a recruitment process. The Office for Human Research Protections (OHRP) provides guidance on IRB membership ('see recommended resources').

- Members: An IRB should be composed of at least 5 members, both men and women, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. There needs to be at least one scientist, one non-scientist, and one person not affiliated with the institution.
- The tribal IRB must determine how it will interpret the term 'institution' and include this information in its policy. Dr. Freeman, former Chair National IHS IRB recommends that the 'non-affiliated' member position be filled by an individual who is not employed by the Tribe (institution), nor has immediate family employed by the Tribe.

NOMINATION

Individuals may be nominated for the position of IRB member based on their experience and/or credentials. An Institutional Official (IO) can nominate the IRB member/s or organizations or departments within the Tribe, Tribal districts or geographical regions of the Tribe may be asked to submit a nomination.

RECRUITMENT

A recruitment process may also be implemented in which an IRB member position can be broadly advertised to solicit applicants or interested individuals. Position or positions can be posted in specific departments or organizations, districts or geographical locations.

- If starting a board with no members, a more general solicitation is recommended.
- If looking to fill the positions for one or two members on the board:
 - Use OHRP guidelines to identify any gaps in expertise and experience and conducted targeted recruitment.
 - Also consider the type of research that is typically reviewed (e.g., biomedical, socio-behavioral)

References:

Bankurt, Elizabeth A and Amdur, Robert J. 2006 Institutional Review Board Management and Function Second Edition. Burlington MA: Jones & Bartlett Learning.

Freeman, William L. Starting an Institutional Review Board: Suggestions for Tribes, Tribal Colleges and Communities.2007.https://depts.washington.edu/ccph/pdf_files/Start_a_Tribal_IRB.pdf

SAMPLE IRB MEMBER RECRUITMENT ADVERTISEMENT

Position Opening

IRB Mission: The mission of _____ Institutional Review Board: *[insert here]*

Responsibilities of IRB Members

- ✓ Actively participate in IRB meetings and offer expertise for the ethical review and monitoring of research
- ✓ Complete training on human subjects protections' regulations and research review processes
- ✓ Attend meetings regularly to help ensure quorum
- ✓ Review research protocols and documents prior to the scheduled meeting
- ✓ Inform coordinator in the event of a conflict of interest for a research protocol
- ✓ Maintain confidentiality regarding research protocols and IRB proceedings

Qualifications

If only looking to fill specific member positions, insert specific qualifications

Scientific Members: Researcher investigator or scientist by profession, able to evaluate the scientific merits of a project

Non-scientific Members: Expertise in non-scientific area, professional or otherwise (ex. culture)

Non-affiliated member: Must not be employed by the _____ Tribe; must not have a family member employed by the _____ tribe

Duration: Length of Term: _____ yrs. **Meetings and Time Commitment:**

The board meets _____ (per month, per quarter) for _____ (number of hours)

Send Letter of Interest and Summary of Qualifications to: *insert contact information*

IRB MEMBER LETTER OF COMMITMENT

_____ Research Review Board Letter of Commitment

Dear IRB Chair/ IRB Coordinator:

I am pleased and honored to serve on the _____ Research Review Board.
I _____ understand that my role as a _____ Research Review Board member will entail the following responsibilities:

- ✓ Actively participate in meetings and offer expertise for the ethical review and monitoring of research
- ✓ Review documents prior to the scheduled meeting, as requested
- ✓ Attend meetings regularly and inform the IRB Coordinator in advance if I am unable to attend the meeting
- ✓ Inform IRB Coordinator in the event of a personal conflict of interest for a research protocol under IRB review
- ✓ Maintain confidentiality regarding research protocols and IRB proceedings at all times

I have read and fully agree to support the Mission, Vision, and Goals of the _____ Research Review Board. I look forward to serving _____ Tribe in this role for the term of _____.

Signed _____ Date _____

Print name _____



ORIENTATION AND TRAINING FOR TRIBAL IRB MEMBERS

ORIENTATION AND TRAINING FOR TRIBAL IRB MEMBERS

This orientation and training consists of three steps. We recommend that step I and III be completed via facilitated in-person meetings. Step II is self-paced and may be completed online in an individual or group setting.

Step I. In the first step, participants will be introduced to the history of human subjects' protections in general and as it relates to American Indian communities.

1. History and Purpose of Human Subjects Protections

Duration: 90 minutes

www.hrsa.gov/publichealth/clinical/HumanSubjects/

3-video series outlines the history of ethics in research and the criteria for protecting human participants in biomedical and behavioral research. Includes a facilitated discussion. Provided by the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

2. "No Meaningful Apology for American Indian Unethical Research Abuses"

Felicia Schanche Hodge, Ethics & Behavior 2012, 22:6, 431-444

Duration: self-paced

[Abstract included in the electronic version of this toolkit](#)

Facilitated discussion of article - outlines the history of unethical medical and research activities involving American Indians since colonization.

3. What is an IRB?

Duration: 7 minutes

<http://www.youtube.com/watch?v=nRhXq-caHXY>

Viewing followed by discussion of brief video created by a Purdue University student providing an overview of the function of an IRB for American Indian Tribal Nations and for researchers working in 'Indian Country'.

4. What Values Will Guide Us?

Duration: self-paced

<http://genetics.ncai.org/which-values-will-guide-us.cfm>

Developed by the National Congress of American Indians (NCAI), this resource is intended to provide American Indian Nations with guidance for determining which values may drive their process of research regulation.

Step II. Following the introduction to human subjects' protections training, participants should obtain a human subjects research certification and complete additional trainings listed below. Through this exercise, participants will gain in-depth knowledge of human subjects' research protections.

1. Human Subjects Research Training Certification

Duration: self-paced

National Institutes of Health (NIH) Protecting Human Research Participants (PHRP) Tutorial (FREE) <ul style="list-style-type: none">• Access here.• This 7 module training outlines the principles used to define ethical research using humans as well as the regulations, policies, and guidance for the implementation of the ethical principles.• Includes certification of completion.	or	CITI Program ‘Human Subjects Research’ course (FEE BASED) <ul style="list-style-type: none">• Collaborative Institutional Training Initiative (CITI) is a provider of research education content. Relevant courses offered include a ‘Human Subjects Research’ series. More information here.• Fee information here.
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2. Is it Human Subjects Research PART 1: Determine if Activity is Research

Duration: 15 min 48 seconds, but self-paced

Developed by CRCAIH, this training uses case studies to provide basic understanding of how to determine if an activity is research. Using an interactive format, participants can learn and test their knowledge in this topic area. (See electronic version of toolkit)

3. Is it Human Subjects Research PART 2: Determine if Research Involves Human Subjects

Duration: 26 min 22 seconds, but self-paced

Developed by CRCAIH, this training uses case studies to provide basic understanding of how to determine if an activity involves human subjects. Using an interactive format, participants can learn and test their knowledge in this topic area. (See electronic version of toolkit)

4. Introduction to Research Data

Duration: 10 min 46 seconds

Developed by CRCAIH, this interactive training provide basic understanding of the various types of research data (See electronic version of toolkit)

5. Review of IRB policies and procedures. In step II, IRB members should also become familiar with their IRB policies and procedures. This exercise provides an opportunity for IRB members to understand how their IRB policies fit with

federal research regulations and recognize any tribally specific regulations that may affect research.

Step III. In step 3, IRB members should review and discuss questions that may have come up during the trainings provided in step II. In this final step, IRB members should conduct a practice IRB review using a sample research protocol and other tools included in the CRCAIH Tribal IRB toolkit.

1. Review and Discussion

Duration: 30 minutes

Facilitated review of questions and topics from Module II, Human Subjects Research Training.

2. Practice IRB Review

Duration: 1 hour

The IRB may use an existing research protocol submitted to the Tribe for the practice review. The should include use of 'research review checklists' and IRB Administration 'review process tools' included in the CRCAIH Tribal IRB Toolkit.

Step IV. Partnerships: It is recommended that new tribal IRB members connect with other established tribal, community or academic IRBs to learn from their experience. It may be beneficial to visit and attend IRB meetings of other established IRBs.



IRB ADMINISTRATION TOOLS

- ◆ The administrative duties of an Institutional Review Board are essential to board functioning. These involve preparation, coordination and documentation of activities before, during, and after IRB meetings. These also include appropriate record keeping of research protocols. The administrative duties, typically conducted by an IRB Coordinator include:
 - Establishing IRB meeting schedules and submission deadlines
 - Serving as the point of contact for research investigators
 - Corresponding on behalf of the IRB
 - Pre-reviewing IRB submissions
 - Monitoring member attendance (including reviewer assignment)
 - Ensuring quorum for IRB meetings

- ◆ This section provides administrative tools to assist with preparation and management of IRB proceedings. These can also serve as training tools for IRB members.
 - Submission Process Flow Charts
 - Investigator Submission Forms
 - Pre-Review Tools
 - Letter Templates
 - Review-Process Tools



SUBMISSION PROCESS FLOW CHARTS

Tribal IRB Review Submission and Review Process Sample Flow Chart A

Principal Investigator (PI) submits required material to Tribal Institutional Review Board (IRB) by submission deadline.

There may a fee associated with the submission.



Tribal IRB Coordinator pre-reviews material

Coordinator requests modifications or additions as needed



Tribal IRB Coordinator includes the research project on the IRB meeting agenda

Coordinator notifies PI of IRB Meeting date and time



Tribal IRB reviews proposed project and makes a determination

Coordinator notifies PI of IRB determination within one week.



Research project may begin after approval is received

No research project activities (including recruitment) may begin prior to the date of the approval letter.

Tribal IRB and Tribal Council Review Submission and Review Process Sample Flow Chart B

**Principal Investigator (PI) submits required materials
to Tribal Institutional Review Board (IRB)
by submission deadline.**

There may be fees associated with the submission.



**Tribal IRB Coordinator pre-reviews material, requests modifications
and includes on IRB agenda**

Coordinator notifies PI of IRB meeting date and time



Tribal IRB reviews proposed project and makes Determination



Tribal IRB approved projects placed on Tribal Council meeting agenda

Coordinator notifies PI of Tribal Council Meeting date and time



Tribal Council reviews proposed project and makes a determination

Coordinator notifies PI of Tribal Council determination within one week.



Research project may begin after Tribal Council approval is received

No research project activities (including recruitment) may begin prior to the date of the approval letter.



INVESTIGATOR SUBMISSION FORMS

- 1. Initial Review**
- 2. Continuation Review**
- 3. Amendment Review**
- 4. Project Termination/Close Out**

Human Subjects Protection Training (CITI or NIH) Completion Date:
Project Related Tasks/Duties:

Other: Student Faculty Sponsor N/A
Email: _____ Phone: _____
Human Subjects Protection Training (CITI or NIH) Completion Date:
Project Related Tasks/Duties:

❖ **FUNDING INFORMATION** : Attach a copy of the budget documentation for the project

No Funding

Private Funding Source:

HHS Center or Institute:

U.S. Department of Health and
Human Services (HHS)

Subcontract or Program Project Grant.
Describe:

❖ **RESEARCHER FINANCIAL CONFLICT OF INTEREST**

- Have you reported a financial conflict of interest to your institution? No Yes
If yes, attach a copy of the 'management plan' or the institution's conflict of interest determination for this research project.
- Do you, your spouse, or dependent children stand to receive financial interest from this research project in excess of \$5,000 in the form of salary or any other payment, not otherwise defined as salary?

No

Yes – Please Describe:

❖ **OTHER IRB and TRIBAL NATION APPROVALS**

- Will study procedures and/or data collection take place at other sites?
 No Yes – List each site:

List any other Institutional Review Boards that have/will review this project. Also list any Approvals or Letters of Support from other Tribal Nations. Attach copies of all approval documentation already obtained. N/A

- ❖ **RESEARCH PROTOCOL/PROJECT DESCRIPTION:** The protocol should include the following, as applicable to the project (please attach a separate document). In this section, please provide a summary in layman’s language of the study design, research question and procedures.
- **Study Design**
Include ‘Research Question’, ‘Scientific Rationale or Background’, Project Description.
 - **Research Procedures**
Include description of all research procedures, including data/specimen collection, processing, and storage procedures. Include description of data collection source, including for e.g. tribal records or environmental resources.
 - **Anticipated Start Date and Completion Date/s for project**
If project has several components, write anticipated start and completion dates for each part; e.g. recruitment, enrollment, intervention, analysis, phases. Include description of duration of intervention and/or interaction with human subjects.
 - **Confidentiality**
Include description of the steps that will be taken to secure data collected and/or protect the participants involved. Describe if ‘identifiers’ will be obtained with the data and remain with the data. Describe who will have access to the data collected. If there will be any transport of data, describe how that will occur and include name and address of all sites where data will be stored.
 - **Informed Consent procedures**
Describe procedures and enclose a copy of each consent form to be used.
 - **Compensation procedures**
Include a description of how participants will be compensated and when in the research process.
 - **Recruitment methods**
Include description of how participants will be recruited. Enclose a copy of recruitment materials to be used; for e.g., flyer, web posting, email, postal letter, scripts for verbal communication. If vulnerable populations are involved, include a description of safeguards for their protection.

- **Privacy**
Describe how participant’s privacy will be protected. For e.g., interviews will be conducted in a private room.

- **Risks and Benefits to Individual Participants**
Describe risks to participants. Also describe potential risks to others who are not participants. Is your project greater than minimal risk? If yes, include your data and safety monitoring plan. Describe benefits to the participants (immediate, long term, direct, indirect); and potential benefit to others who are not involved in the research project. Provide detailed response.

- **Risks and Benefits to Tribal Nation**
Please address any risks to Tribal communities involved? Could your project present risk to the resources (e.g. environmental, plant life, wildlife) within the reservation? Describe plan to minimize risks to the Tribe and/or Tribal communities. Has appropriate (reservation) department or organizational permissions been granted? Describe benefit to the Tribe and/or Tribal communities (immediate, long term, direct, indirect). Include description of any benefit to society or others.

- **Results Dissemination**
Describe plan. Include plan for sharing of results with Tribal community.

- **Data sharing**
Please include a plan for long term storage and sharing of data for future use.

❖ **PARTICIPANT INFORMATION**

Vulnerable Populations: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A	
Describe Participants. Check all that apply:	
<input type="checkbox"/> Children <input type="checkbox"/> Adolescents <input type="checkbox"/> Adults <input type="checkbox"/> Pregnant Women <input type="checkbox"/> Fetuses and/or neonates <input type="checkbox"/> Prisoners	<input type="checkbox"/> Cognitive or Mental impairment <input type="checkbox"/> Physical impairment or disability <input type="checkbox"/> Economically or socially disadvantaged <input type="checkbox"/> Other:

<input type="checkbox"/> Male <input type="checkbox"/> Female:
Age Range:
Planned Enrollment Number:
Explain choice of participant population:
Description of Inclusion and Exclusion Criteria:
Planned Participation Duration:

❖ **ASSURANCES**

By signing below, I attest to the following:

The information provided in this form and attached documentation is true. I will not begin my research until I have received written approval from the IRB. I will abide by _____ Tribe policy for research conducted within the exterior boundaries of the reservation.

Signature _____

Printed Name:

Principal Investigator

Signature _____

Printed Name:

Faculty Supervisor (if student researcher)



❖ List other reservation resources used in this research study in the past year (e.g., land, water, plant life, wildlife, historical records or artifacts) and indicate if use of these resources will continue in the next year: N/A

❖ Have all forms of data collection for the research project been completed? Yes
 No Additional Comments:

❖ List any research products created in the last year (e.g., abstracts, conference presentations, publications, media releases)? Yes, documents attached
N/A

Date (Submission/ Presentation/ Publication)	Author/s or Presenter/s	Title	Format (poster, presentation, manuscript PMID)

I certify that the information provided in this application, including attachments, is true.

Principal Investigator Signature

Date

AMENDMENT APPLICATION

Submission Date:

Recent IRB Approval Date:

Research Protocol Title:

Principal Investigator:

Institution:

Research Study Contact:

Email:

Phone:

❖ **AMENDMENT/S TO RESEARCH STUDY (Select all that apply)**

1. **Research Plan.** Describe and provide justification for change. Attach research plan with changes evident as track change mark ups.

2. **Recruitment materials or process.** Describe and provide justification for change. Attach research plan with changes evident as track change mark ups.

3. **Consent Process and/or Document/s.** Describe and provide justification for change. Attach research plan with changes evident as track change mark ups.

4. **Research Instruments.** Describe and provide justification for change. Attach research plan with changes evident as track change mark ups.

5. **Other.** Describe and provide justification for change. Attach research plan with changes evident as track change mark ups.

❖ **RISK/BENEFIT ASSESSMENT**

1. Will the changes affect the risk/benefit ratio of the project? Yes No
If 'Yes', please describe.

❖ **RECONSENT**

1. Consent form or Consent process changes? Yes No
2. Will participants need to be re-consented? Yes No
If 'yes', describe the plans for re-consent (e.g. within 30 days, at next visit)

❖ **AMENDMENT TO KEY RESEARCH PERSONNEL** N/A

1. **Change of Principal Investigator (PI)**

Explain the reason for the change. Also explain if the current PI will remain on the research project in another capacity. If applicable, provide an overview of their new role. Include a brief bio indicating the relevant expertise of the individual replacing the current principal investigator. Also attach the new PI's CV and certificate of human subjects' protections training.

2. **Other Key Personnel Additions:**

Attach a document listing the individuals added to the research team in alphabetical order by surname. In a separate file, attach all of the human subjects' protections

training certificates for new additions. Include the following information for each individual added to the research team:

- Full Name
- Date of Completion for Human Subjects Training
- Organizational Affiliation
- Role in the Research Study (e.g., recruitment, informed consent, intervention, data collection, data analysis, project management, project coordination, research oversight)

3. Other Key Personnel Removals:

Attach a document listing the full names of the individuals being removed in alphabetical order by surname.

I certify that the information provided in this application, including attachments, is true.

Principal Investigator Signature

Date



PROJECT TERMINATION/CLOSE-OUT REPORT

Submission Date: Project Start Date: Recent IRB Approval Date:

Research Protocol Title:

Principal Investigator:

Institution:

Research Study Contact:

Email:

Phone:

1) Project Status

Project completed, select all that apply:

Enrollment closed

Follow up completed

Data

collection completed

Data analysis completed

Project ending early, incomplete

Project never initiated, enrollment not started, closing study

Additional information explaining reason for closure:

2) Provide a summary of the findings from the research project and their implications. Use layman's language (avoid technical or field-specific language).

Include information about how the project findings and data: a) could be beneficial to the Tribe, b) could inform future research, including specific suggestions for secondary uses of the data. Explain study limitations and lessons learned in the course of the project. Share how you plan to share research results with participants (if applicable) and with _____ Tribe community.

- a. List any research products created in the last year (e.g., abstracts, presentations, publications, media releases)? Yes, documents attached
 N/A

Date (Submission/ Presentation/ Publication)	Author(s) or Presenter(s)	Title	Format (poster, presentation, manuscript PMID)

3. Number of participants from _____ Tribal Reservation enrolled in this study:
 N/A

- a. Participation Discontinued N/A

- I. Enter the number of individuals who voluntarily discontinued participation in the research study in the last year:
- II. Enter the number of individuals that were removed by the investigator:

4. Are any other study sites still open? Yes No N/A

Additional Information:

5. Was there an unanticipated problem, protocol deviation or adverse event in the past year?

- Yes No Documents Attached

If 'Yes', please describe the event and attach a copy of any applicable reports filed.

6. List other reservation resources used in this research study in the past year (e.g. land, water, plant life, wildlife, historical records or artifacts): N/A

Additional information:

I certify that the information provided in this termination/closeout report, including attachments, is true. I will comply with the _____ Tribe's policies regarding the ownership and return of research data.

Principal Investigator Signature Date





PRE-REVIEW TOOLS

- 1. Pre-Review Checklist**
- 2. Determine if Activity is Research
Flow Chart**
- 3. Determine if Research Involves
Human Subjects Flow Chart**

TRIBAL IRB PRE-REVIEW CHECKLIST

TYPE OF SUBMISSION

- Application for Initial Review Final Report/Closure
- Application for Continuation Response to IRB Request
- Amendment Other:

INITIAL REVIEW NEW PROTOCOLS ONLY

1. Determine if the activity is research. Refer to 'Determine if Research' flowchart
2. Determine if activity involves human subjects. Refer to 'Determine if Activity Involves Human Subjects' flow chart.
3. Determine if the research is within the jurisdiction of the Tribe, i.e. on reservation land.
4. Identify relevant Tribal, state, federal, or international law that may apply to the research. Reference federal and international research protection laws in these resources:
[Human Research Protections Standards & Regulations](#)
[Application of Research Protections Standards & Regulations](#)
5. Review application form and/or documents submitted. Check for missing material.
6. If missing material is found, send letter to the investigator requesting this information. If application complete, schedule the project on the next IRB meeting agenda. Send a letter to the investigator notifying them of scheduled date. See 'Letter Templates'.
7. Check to see if the investigator is already listed in the IRB records (for conducting research on the reservation previously). If not, enter contact information, CV, and human research protections certifications into IRB records.
8. Determine the board member expertise that is most relevant for review of this research project. Identify what special determinations the IRB needs to make in order to approve the submission (e.g. risk to vulnerable populations). If board member expertise is not sufficient, a consultant may be needed.

Notes:

CONTINUING REVIEW PROTOCOLS ONLY

1. Look for changes in the submission from the most recent approval.
2. If applicable, check whether the consent forms and scripts being used are the most recently approved versions.
3. If needed, communicate with the investigator regarding missing material or to resolve any questions about the material submitted for 'continuation review'.
4. If application complete, schedule the submission for continuation on the next IRB meeting agenda. Send a letter to the investigator notifying them of scheduled date. Refer to 'Letter Templates'.
5. Send the "Continuation Review Checklist" together with the submission materials for review, at least two weeks prior to the scheduled board meeting.

RESPONSES TO IRB REQUESTS

1. Review relevant minutes and determine if the investigator responded to the request appropriately (e.g. made required modifications or provided additional information). Communicate IRB response to investigator. Refer to 'letter templates'.

Notes:

PROJECT TERMINATION/CLOSE OUT

1. Ensure that the investigator has submitted a completed 'Project Termination/Close Out' Report form. Check for missing information.
2. Determine if any new information about the research project has been provided. (e.g. new risk to participants or the Tribe).
 - a. If 'yes', schedule the project on the next IRB meeting agenda.
3. If applicable, ensure that the investigator has submitted a completed 'Data Return Form' and accompanying materials.
4. If needed, communicate with the investigator regarding missing material or to resolve any questions. If determined that project close-out will be on an IRB agenda, send investigator communication regarding this. Refer to 'Letter Templates'.

5. Once verified that all material has been received, send a letter to investigator acknowledging receipt. Refer to 'Letter Templates'
6. Ensure files of project information contain all research submissions from the investigator and all records of correspondence between the IRB and the investigator.
7. If applicable, ensure that data returned by the investigator is filed correctly.

Notes:

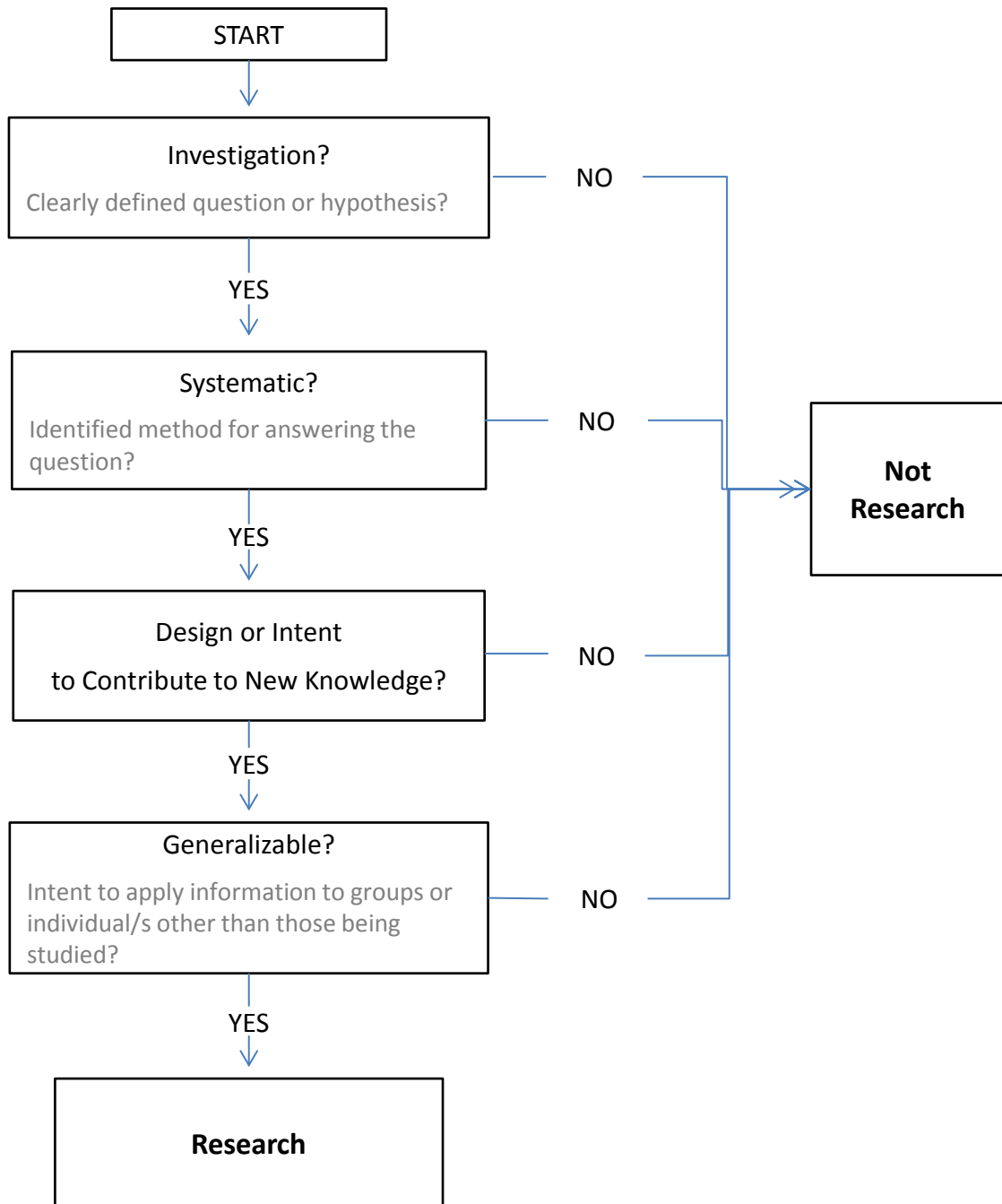
OTHER SUBMISSIONS

1. Review application form and/or documents submitted for missing material.
2. If missing material is found, send letter to the investigator requesting this information.
3. If all submitted material is complete, choose the relevant form of written communication to the investigator. (e.g. send letter to investigator confirming submission, or schedule item on the next meeting agenda and send letter with the date). Refer to 'Letter Templates'.
4. If the submission requires board review, identify what special determinations the IRB needs to make in order to approve the submission (e.g. risk to vulnerable populations) and prepare appropriate checklists and supplemental reference material for the board.
5. If applicable, identify relevant Tribal, state, federal, or international law that may apply to the research. Reference federal and international research protection laws in these resources: [Human Research Protections Standards & Regulations](#) [Application of Research Protections Standards & Regulations](#)

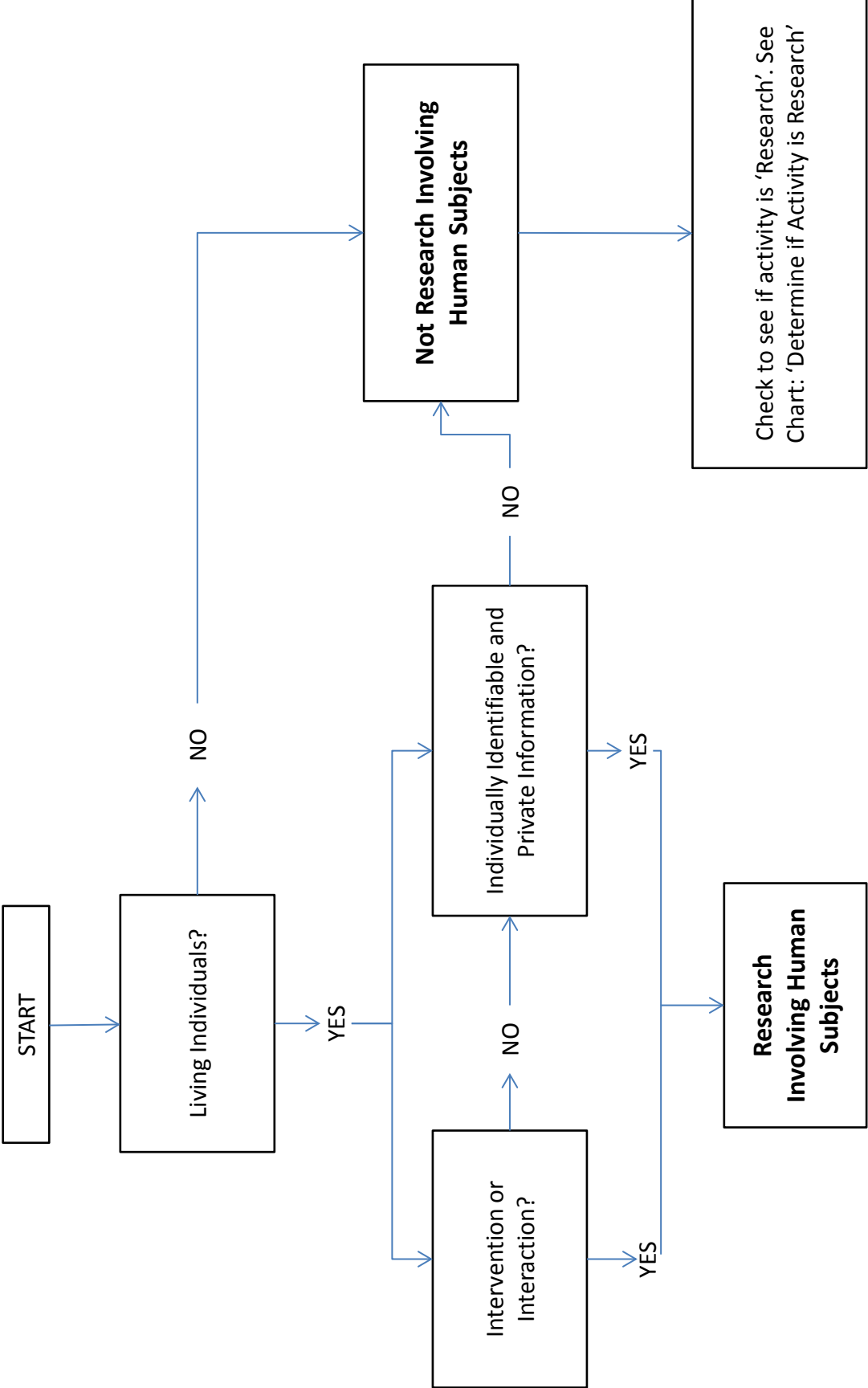
Notes:

Determine if Activity is Research

Research means a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. **45 CFR §46.102**



Determine if Research Involves Human Subjects







LETTER TEMPLATES

- 1. Approval Letter**
- 2. IRB Receipt and Meeting Notification**
- 3. Request for Missing Information**
- 4. Table or Disapprove**

IRB APPROVAL LETTER

DATE:

RE: Study Title:

Principal Investigator Name:

Approval Period:

Dear _____

The submission for (*insert here: e.g. 'Initial Review', 'Continuation Review', 'Amendment Approval', 'Presentation Approval'*) of the above referenced research project has been approved by the _____ Tribe Institutional Review Board (IRB).

The research project has been approved for the period noted above. If the project duration will be more than one year, an "Application for Continuation/Renewal" must be submitted to the board prior to the expiration of the protocol, in accordance with the IRB submission deadlines.

If the project has ended, a "Project Termination/Close out Report" must be submitted along with the "Data Return form" if applicable.

Any amendments or changes to the research project must be reported and approved by the board prior to implementation.

If you have additional questions or concerns, please contact the IRB Coordinator at (*insert contact information*).

Sincerely,

IRB Coordinator, _____ Institutional Review Board

IRB MEETING NOTIFICATION LETTER

DATE:

RE: Study Title:

Principal Investigator Name:

Dear _____

This letter is to acknowledge receipt and pre-review of the following items for *(insert study title)*:

1. *Application (e.g. Continuation or Initial Review)*
2. *Insert Item Name (e.g. Protocol)*
3. *Insert Item Name (e.g. Informed Consent Document)*

This project has been scheduled for Tribal IRB review on *(insert date)*. If we can be of further assistance, please contact the IRB Coordinator at *(insert contact information)*.

Sincerely,

IRB Coordinator, _____ Institutional Review Board

REQUEST FOR INFORMATION LETTER

DATE:

RE: Study Title:

Principal Investigator Name:

Dear _____

This letter is to acknowledge receipt and review of your submission for *(insert study title)*. The following items are missing and/ or we have additional questions:

Please submit the clarifications as soon as possible. This project cannot be reviewed or approved until the aforementioned items have been addressed. Please contact the IRB Coordinator for additional questions at *(insert contact information)*.

Sincerely,

IRB Coordinator, _____ Institutional Review Board

IRB OUTCOME LETTER

DATE:

RE: Study Title:

Principal Investigator Name:

The submission for (*insert here: e.g. 'Initial Review', 'Continuation Review', 'Amendment Approval', 'Presentation Approval'*) of the above referenced research project has been (*insert here*) 'tabled' or 'disapproved' by the _____ Tribe Institutional Review Board (IRB).

The rationale for this IRB decision is as follows:

- 1.
- 2.
- 3.

Option if Tabled: Please provide us with the requested modifications and/or additions. In the meantime the research protocol has been placed on the agenda of the next scheduled IRB meeting, (*insert date*).

Option if Disapproved: Please do not hesitate to contact us if you have any questions about this decision.

If we can be of further assistance, please contact the IRB Coordinator at (*insert contact information*).

Sincerely,

IRB Coordinator, _____ Institutional Review Board



REVIEW PROCESS TOOLS

Before Meeting

- **IRB Meeting Preparation**
- **IRB Meeting Roster**

During Meeting

- **IRB Meeting Minutes Template**
- **IRB Review Process**

IRB MEETING PREPARATION

Prior to the IRB Meeting:

- 1) Determine items for the IRB meeting agenda (two weeks minimum prior to the scheduled IRB meeting).
Use “IRB Meeting Minutes Template” to help determine agenda items.
(If investigator is required to attend meeting in person, notification earlier is better to accommodate flight and travel arrangements.)
- 2) Send written correspondence to research investigators that are required to participate.
- 3) Reserve meeting space and order any refreshments to be served.
- 4) Determine which IRB members, alternates, or consultants are needed for this meeting (given the subject matter of the items on the agenda).
- 5) Email or phone the board members requesting confirmation of attendance at the meeting.
- 6) Once confirmations received, complete the IRB Meeting Roster for the scheduled meeting, included the applicable ‘Reviewer Checklists’.
- 7) Send primary reviewer/s and other board members the materials to be reviewed for the scheduled meeting.
- 8) Complete any photocopying or collating of materials needed.

The day of the meeting:

- 1) Set up the room, table, and chairs to accommodate all who will be present.
- 2) Set up technical equipment (e.g. videoconferencing or teleconferencing equipment, projector, audio recorder)
- 3) Have laptop handy with electronic reference materials open. Have hardcopy reference materials ready.
- 4) Have a sign-in sheet ready. (Cross-check the sign in sheet with the IRB meeting roster)
- 5) Have confidentiality statement for guests to sign
- 6) Set up refreshments.

TRIBAL IRB MEETING MINUTES TEMPLATE

MINUTES RECORDED BY:

DATE: **MEETING START TIME:** **MEETING END TIME:**

PRESENT:

- | | | |
|--------------------------------------|--------------------------------------|---|
| <input type="checkbox"/> Member Name | <input type="checkbox"/> Member Name | <input type="checkbox"/> Alternate Name |
| <input type="checkbox"/> Member Name | <input type="checkbox"/> Member Name | <input type="checkbox"/> Alternate Name |
| <input type="checkbox"/> Member Name | <input type="checkbox"/> Member Name | <input type="checkbox"/> Alternate Name |
| <input type="checkbox"/> Member Name | | |

MEMBER SUBSTITUTION:

Name of Alternate	Member Absent

NUMBER OF MEMBERS PRESENT AT MEETING START:

GUESTS:

Name	Institutional/Other Affiliation

DOCUMENTATION OF CONFLICT OF INTEREST:

Member Name	Agenda Item and Description of Conflict	Recused?
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No

DOCUMENTATION OF TEMPORARY SUSPENSION OF MEETING:

Time Meeting Halted	Excused Member Named	Time Meeting Resumed

PRE-MEETING BUSINESS/ANNOUNCEMENTS:

--

REVIEW OF MINUTES FROM PREVIOUS MEETING:

<input type="checkbox"/> Accept as is <input type="checkbox"/> Revise and Resubmit
IRB Action Items:

EXPEDITED ITEMS (if applicable):

Item Name	Principal Investigator & Institution	IRB Determination

OTHER ITEMS:

Item	Comments/ Discussion Points

OLD BUSINESS

Tabled Research Protocols (if applicable):

Protocol Name:		
Principal Investigator Name:	Institution:	
Summarize any discussion of major controverted issues:		
IRB Action Items/Other Notes(e.g. member leaving room for conflict of interest):		
Voting Results: # For # Against #Abstained		
Final Determination: <input type="checkbox"/> Approve <input type="checkbox"/> Approve with Modifications <input type="checkbox"/> Disapprove <input type="checkbox"/>		
Table		
Summarize rationale for determination and/or modifications requested:		

NEW BUSINESS:

New Research Continuation Amendment Research Presentation Publication

Protocol Name:		
Principal Investigator Name:	Institution:	
Summarize any discussion of major controverted issues:		
IRB Action Items/Other Notes(e.g. member leaving room for conflict of interest):		
Voting Results: # For # Against #Abstained		
Final Determination: <input type="checkbox"/> Approve <input type="checkbox"/> Approve with Modifications <input type="checkbox"/> Disapprove <input type="checkbox"/>		
Table		



CONVENED IRB MEETING REVIEW PROCESS

Conflict of Interest	<ul style="list-style-type: none">• IRB Checks for IRB member conflict of Interest prior to research review• Reviewed for all research protocols on the agenda
Quorum	<ul style="list-style-type: none">• Ensures quorum is present for each research protocol
Overview of Research	<ul style="list-style-type: none">• Primary reviewer or IRB Chair provides overview of research protocol
Discussion and documentation	<ul style="list-style-type: none">• IRB discusses protocol and questions for investigator• IRB documents how controversial issues are resolved
Criteria for approval of research	<ul style="list-style-type: none">• IRB reviews Criteria for approval
Voting	<ul style="list-style-type: none">• IRB Votes - documents votes 'for', 'against' and 'abstain'
Document IRB Determination	<ul style="list-style-type: none">• Documents IRB determination and proceeds to next item on the agenda



REVIEWER CHECKLISTS

These checklists are designed to be used by IRB members in the review of research applications. The checklists incorporate both federal guidelines for the review of human subjects' research as well as guidelines to ensure community protections for Tribal Nations.

These checklists can also be used as training tools for initial and on-going training of IRB members.

1. Initial Review
2. Continuation Review
3. Informed Consent Review
4. Protocol Amendment Review
5. Protocols Involving Pregnant Women and Fetuses
6. Publication and Presentations Review



INITIAL, CONTINUATION & PUBLICATION REVIEW CHECKLISTS

IRB REVIEWER CHECKLIST - INITIAL REVIEW

Project Title

Principal Investigator	Institution

Reviewer Conflict of interest and Tribal IRB Jurisdiction

1) Do you have any conflict of interest (personal, financial, academic, or other interest) that could influence your review of this protocol?

- Are you in any way involved in the design or conduct of the study?
- Is your spouse, or immediate family member involved in the conduct of this research study?
- Is your advisor, mentee, or student involved in the conduct of this research study?
- Do you receive income from the institution supporting this study, or do you stand to receive a financial benefit from the conduct of the research?
- Do you receive income or stand to receive a financial benefit from a company whose business is substantially related to the subject matter of the research?

Yes

No

If yes, or you think you might have another type of conflict of interest please bring it to the IRB Chair and/or board's attention ***before*** continuing to review this research submission.

--

Review of Research Plan

1) Are there any drugs being used in this study?

Yes

No

If yes, the device must be approved by the FDA, for use in research.

2) Are there any investigational devices being used in this study?

Yes

No

If yes, the device must be approved by the FDA, for use in research.

3) Does the research design appear to be adequate for the question?

Yes

No

4) Have all relevant letters of support been obtained?

Yes

No

5) Do the study personnel have the appropriate qualifications

Yes

No

6) Do all key personnel have human subjects training?

Yes

No

7) Are the facilities to be used for this study adequate?

Yes

No

8) Are any medical or psychological resources that participants may need as a result of their participation in the research available and adequate?

Yes

No

9) Is the research on a topic, or involve methods or results that could potentially cause community harm?

Yes

No

For example cause collective physical or social harm, affect sovereignty, or conflict with Tribal values/ beliefs.

If 'Yes', make a note of your concerns to bring up for discussion in the board meeting.

Involvement of Individuals from the Tribe

1) Does the research involve a vulnerable population/s? :

- Children
- Pregnant women
- Fetuses and/or neonates
- Prisoners
- Cognitive or mental impairment
- Physical impairment or disability
- Economically or Socially Disadvantaged
- Other vulnerable populations?

Please describe

2) Does the research involve use of genetic material?

Yes

No

3) Subject Selection and Recruitment Methods:

a. Clear and justified inclusion/exclusion criteria:

- Is it clear who will be eligible to participate in the study? Yes No
- Are all tribal members getting an equal opportunity to participate in the research?
 Yes No

b. Is the targeted population appropriate, given the topic and purpose of the research?

Yes No

c. Are the methods of recruitment clearly described and acceptable?

Yes No

d. Do the methods of recruitment avoid coercion or undue influence?

Yes No

(For more detailed description of 'coercion' and 'undue influence', see the CRCAIH Glossary of Human Subjects Protections Terms.)

Risks and Benefits

- 1) Is research more than minimal risk? Yes No
(For definition of 'minimal risk', see the CRCAIH Glossary of Human Subjects Protections Terms)
- For more than minimal risk research, is the risk justifiable for the targeted individuals and/or for the Tribe? Yes No
- 2) Are the risks/potential harms clearly described? Yes No
(E.g. physical, psychological, social, legal, economic harm)
- 3) Is a plan for addressing participant injury/illness described? Yes No

Use/Collection of Data or other Resources from the Tribe

*[Land, water; plant life; wildlife; historical records or artifacts; cultural records, artifacts, practices]

- 1) Does it correlate with the research plan and/or lay summary? Yes No
- 2) Have appropriate permission/s for access and use obtained Yes No
- 3) Will the use/collection of the data/resources harm the source in any way? Yes No

RESEARCH CONTINUATION/RENEWAL

Protocol Title:

Principal Investigator:

Institution:

Do you have any conflict of interest (personal, financial, academic, or other interest) that could influence your fair and objective review of this protocol for re-approval?

- Are you, your spouse, or immediate family member involved in the conduct of this research study?
- Is your advisor, mentee, or student involved in the conduct of this research study?
- Do you receive income from the institution supporting this study, or do you stand to receive a financial benefit from the conduct of the research?
- Do you receive income or stand to receive a financial benefit from a company whose business is substantially related to the subject matter of the research?

Yes

No

If yes, or you think you might have another type of conflict of interest please bring it to the IRB Chair and/or board's attention ***before*** continuing to review this research submission.

Comments/Additional Information:

Review of Research Plan

1) Indicate the type of continuation:

Extension of study without study changes/modifications

Extension of study with study changes/modifications: If changes present, please review 'amendment' application submitted by investigator

2) Is the current study protocol (including any proposed changes) more than minimal risk to the individual, community, and/or Tribe?

Yes

No

Not Applicable

If yes, have adequate protections and safeguards been put into place?

Yes

No

3) Was a protocol deviation or adverse event report filed in the past year?

Yes

No

If yes, was the event addressed adequately?

Yes

No

4) Have there been any complaints about this research?

Yes No

If yes, were these complaints investigated and/or addressed adequately?

Yes No

Comments/Items for Board Discussion:

Involvement of Human Subjects

1) Are the risks to the individuals involved reasonable in relation to the anticipated benefits?

Yes No Not Applicable

2) Were there any complaints or concerns raised about the research by the participants and/or community in the last year?

Yes No

3) Does the number of individuals enrolled correspond to the number approved for enrollment?

Yes No Not Applicable

4) Is the number of participants who discontinued participation in the last year a reason for concern?

Yes No Not Applicable

5) Is the consent process originally approved by the IRB still appropriate?

Yes No Not Applicable

5) Have there been any significant new findings or changes to the research that might reasonably affect participant's willingness to continue in the research?

Yes No Not Applicable

If yes, has participant re-education and possible re-consent been addressed?

Yes No

Comments/Items for Board Discussion:

Review of Products and Publications Resulting from Research

1) Have any products resulting from this research (e.g., abstracts, posters, presentations, publications, media releases) proved to present more than minimal risk to the individuals involved, community involved, and /or the Tribe?

Yes No N/A

Comments/Items for Board Discussion:

Use/Collection of Data or other Resources from the Tribe

(Land, water, plant life, wildlife, historical records or artifacts, cultural records, artifacts, practices)

1) Have there been any reports of misuse or harm to tribal land, resources, and/or property in the last year, resulting from research study activities?

Yes No N/A

If yes, is there adequate explanation to indicate that the study is safe to proceed as planned?

Yes No

2) Will relevant use/access permissions (from individuals or departments) be valid for another year?

Yes No N/A

3) Will the continued use/collection of data/resources (including any proposed changes) harm the source in any way?

Yes No N/A

Comments/Items for Board Discussion:

Resource to Guide Review: [OHRP Guidance on IRB Continuing Review of Research](#)

PUBLICATIONS REVIEW CHECKLIST

Protocol Title:

Principal Investigator:

Institution:

1. Has a layman's summary been included with this publication?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
	<input type="checkbox"/> N/A
2. Does the layman's summary provide adequate information about the purpose and results of research?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
3. Is this publication consistent with the topic and procedures outlined in the informed consent used in the research protocol?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
4. Does this publication present risk for community harm (e.g. violations of Tribal law, policy, customs or stigmatization)?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
5. Will it be beneficial to the Tribe to be identified in this publication?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No



INFORMED CONSENT & PREGNANT WOMEN AND FETUSES CHECKLISTS

INFORMED CONSENT CHECKLIST

Protocol Title:

Principal Investigator:

Institution:

Study Title and Overview **All must be true**

- Name of the study is clearly stated and matches the protocol title
 - There is 'Inclusion and exclusion criteria' for participation
 - Maximum number of subjects anticipated is stated.
-

Study Purpose **All must be true**

- There is a statement that the study involves research. Study procedures are described in a non-technical lay language (detailed and clear description of what participant is required to do, for e.g. include description of types of questions that will be asked, step by step process for physical procedures.)
 - The number of times that a procedure or study component will be performed and the duration of each session of participation is explained.
 - The participants' overall time commitment is stated.
-

Voluntary Participation **All must be true**

- Statement to indicate that participation is voluntary.
 - Refusal to participate will not result in loss of benefits or penalty
 - Individual can withdraw at any time.
 - There is a disclosure of appropriate alternatives to participating in this research study
-

Risks and Discomforts **All must be true**

- There is a description of **foreseeable** risk or discomforts (for e.g. social, physical, psychological, economic, legal, privacy)
- There is a description of **unforeseeable** risks or discomforts

- For more than minimal risk studies, there is a statement regarding compensation and/or medical treatment for research-related injury. There is language regarding who to contact in case of research-related injury.

Participant Confidentiality **All must be true**

- If applicable, statement describing who will have access to participant's identifying information and the efforts to maintain confidentiality.
 - A statement describing how and where data will be stored, for how long, as well as if data will be shared.
-

Participant Benefits **All must be true**

- Description of any benefits to participant or others
 - If applicable, statement that there will be no tangible benefits to the participant
-

Participant Compensation **All must be true**

- Statement clearly describing if the participant will be compensated for participating in the research
 - A description of the amount and type of compensation
 - The compensation will not constitute 'coercion' or 'undue influence'.
 - If applicable, statement that the participant will not be compensated
-

Researcher Contact Information **All must be true**

- Name and telephone number of someone to contact with questions about the research
 - Name and telephone number of someone to contact about a research-related injury, mistreatment, and/or with concerns about participant rights
-

Participant or Legal Representative signature (unless documentation of consent is waived)

All must be true

- Statement that the individual will receive a copy of the consent form that s/he signs.
- There is no language that causes the individual to waive, or appear to waive any legal rights by signing the document.

Exculpatory Language **All must be true**

There is no language releasing the investigator, sponsor, institution, or its agents from liability for negligence.

Resources to Guide Review

- [CRCAIH Glossary of Human Subjects Protections Terms](#)
- [45 CFR part 46.116, 46.117 , General Requirements for Informed Consent](#)

PROTOCOL INVOLVING PREGNANT WOMEN &/OR FETUSES

Protocol Title:

Principal Investigator:

Institution:

1) Have similar pre-clinical studies, such as studies on pregnant animals, or studies on non-pregnant women been conducted to provide information for assessing the potential risks for pregnant women and/or fetuses?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
	<input type="checkbox"/> N/A
2) Is it true that the biomedical knowledge or other knowledge to be obtained as a result of this research can be obtained by no other means?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
3) Does the consent process fully inform the woman recruited of any foreseeable impact of the research on the fetus? Use the Consent form checklist to review the details of the actual consent document.	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
4) Have the risks to the pregnant woman and fetus been minimized?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
5) Is the pregnant woman a child, as defined by state law? If unsure, check state laws to find out what the legal age of adulthood is. If yes, then regulations for research involving children also need to be complied with. See 45 CFR 46.402 and 45 CFR Subpart D	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
6) Is it stated in the protocol that individuals engaged in research are prohibited from incentives (monetary or otherwise) to encourage termination of the pregnancy?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No
7) Is it stated in the protocol that individuals engaged in research are prohibited from taking part in decisions regarding the timing, method, or procedures to terminate a pregnancy?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No

Determination of Who Needs to Give Consent:

A. Only the pregnant woman needs to give consent if any and/or several of the following are true:

- The research holds no prospect of direct benefit to the woman or the fetus
- The risk to the fetus is not greater than minimal
- The purpose of the research is to develop important biomedical knowledge

Look for evidence of each of the items above in the research protocol and other submitted documents.

B. Only the pregnant woman needs to give consent if one of both of the following are true:

- The research holds the prospect of direct benefit to the pregnant woman only.
- The research holds the prospect of direct benefit to both the pregnant woman and the fetus.

C. Both the pregnant woman and the father of the fetus need to give consent if the following are true:

- The research holds the prospect of direct benefit to the fetus only.

The consent from the father does not have to be obtained if he is unavailable, incompetent, temporarily incapacitated, or if the pregnancy resulted from rape or incest.

Key Terms (45 CFR 46.202)

Fetus - The product of conception from implantation until delivery.

Dead Fetus - A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

Delivery - Complete separation of the fetus from the woman by expulsion or extraction or any other means.

Pregnancy - Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Viable - As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

Specific Concerns/Items for Board Discussion:

Resources to Guide Review:

- [Federal Regulations for Research Involving Pregnant Women/Fetuses: 45 CFR 46 Subpart B](#)
- [CRCAIH Glossary of Human Subjects Protections Terms](#)

RECOMMENDED RESOURCES

RECOMMENDED RESOURCES

CRCAIH Resources

1. Glossary of Human Subjects' Protections Terms -
http://crcaih.org/assets/Human_Subjects_Protections_Glossary.pdf
2. A Collection of Ethical Standards and Resources on Human Subjects' Protections-
<http://crcaih.org/zoo-category/item/human-research-protections-standards-regulations.html>
3. Application of Standards and Regulations for Human Subjects Protections: A handbook of resources – http://crcaih.org/zoo-category/item/application-of-research-protections-standards-regulations.html?category_id=11

Additional Resources

1. Human Subjects Research (45 CFR 46) -
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
2. Federal Wide Assurances (FWA)-
<http://www.hhs.gov/ohrp/assurances/assurances/index.html>
3. Sample IRB Authorization Agreement-
<http://www.hhs.gov/ohrp/assurances/forms/irbauthorizpdf.pdf>
4. National Congress of American Indians (NCAI) Policy Research Center -
<http://www.ncai.org/initiatives/ncai-policy-research-center>





