# Southwest Tribal Institutional Review Board

# Research Proposal Submittal Checklist

# (to be submitted with packet)

Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Submitted to Southwest Tribal IRB: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SWT IRB # (leave blank if unassigned): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

A research packet must contain the following items to be considered complete:

|  |  |
| --- | --- |
| **Item** | **Page #/ appendix** |
| 1. Signed cover letter |  |
| 1. A clear and complete description of the research to be conducted. |  |
| 1. A copy of the consent form. |  |
| 1. Information on the consent process. |  |
| 1. If applicable, copy of the assent form. |  |
| 1. If applicable, information on the assent process. |  |
| 1. If the Principal Investigator or Co-Investigator is faculty of a university or institution, a copy of the university or institution’s IRB decision needs to be submitted. |  |
| 1. If applicable, a copy of the Service Unit approval letter. |  |
| 1. A copy of the tribal approval letter from each participating tribe. |  |
| 1. A copy of proposed procedures to maintain confidentiality and anonymity. |  |
| 1. If the proposal includes a survey or questionnaire, copies need to be submitted. |  |
| 1. CV’s or resume of all project staff **(No more than 5 pages)** |  |
| 1. Budget |  |
| 1. Timeline |  |
| 1. Proof of human subjects’ protection training completion for key research personnel, especially those working directly with the community. |  |
| 1. Procedure for adverse events. |  |
| 1. Funding source(s) disclosure. |  |
| 1. Signed principal investigator assurance |  |

**NOTE: paginate and label all appendices and attachments.**

One complete original SW Tribal IRB Application (signed) and 8 copies must be sent no later than the submission due date to:

**Attn: Rachell Tenorio, MSW, PhD  
SW Tribal IRB Coordinator**

**Albuquerque Area Indian Health Board**

**7001 Prospect Place NE**

**Albuquerque, NM 87110**

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# Southwest Tribal Institutional Review Board

# NEW APPLICATION

**SWT IRB Research Protocol #**(leave blank if unassigned): \_\_\_\_\_

**Current Title of Protocol:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**NOTE: PLEASE COMPLETE ALL QUESTIONS** *(Paginate and label all appendices and attachments):*

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# Part A: Contact Information

**A1. Principal Investigator’s name, address, telephone, fax, and e-mail (please note** all official IRB correspondence will be sent to this address**):**

|  |  |
| --- | --- |
| **Name:** | **Email:** |
| **Phone:** | **Fax:** |
| **Title:** | **Dept:** |
| **Address:** | |
| **CITI Training Current (within last 2 years)**  Yes  No | |

Is the PI the Primary Admin Contact? YES  NO

**If you answered no, please include Primary Administrative contact information for IRB Correspondence:**

|  |  |
| --- | --- |
| **Name:** | **Email:** |
| **Phone:** | **Fax:** |
| **Title:** | **Dept:** |
| **Address:** | |
| **CITI Training Current (within last 2 years)**  Yes  No | |

**A2. Please list other research personnel involved with the project: (i.e. co-PI, research assistant, field coordinators, etc.) Provide personnel name, role on research project and a brief description of their role:**

|  |  |  |
| --- | --- | --- |
|  | **Research Team Members** | **Role on Research Project** |
|  | Name: | Role: |
|  | Brief Description of Role: | |
|  | Name: | Role: |
|  | Brief Description of Role: | |
|  | Name: | Role: |
|  | Brief Description of Role: | |

*Note: Please include all Research Team Members, human protections Training, Resume/CVs (no more than 5 pages).*

# Part B: Research Description

B1. **PURPOSE**  *Include research question or provide hypothesis, aims and objectives of the research project:*

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| --- |
|  |

B2. **BACKGROUND** *Summary of recent relevant literature or findings about research topic, including reports of multi-center trials, with particular attention to risks (attach citations/bibliography or additional sheets if needed)* ***Please label as an Appendice****.*

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B3. **METHODS** *Please include research summary to include research procedures and methods, and other information pertinent to your research study (attach project timeline, survey or questionnaire, & additional document(s) if necessary)*

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B4. **DATA USE** *Provide a description of how data will be used, collected, stored, maintained and destroyed.*

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B5. **ADVERSE EVENTS** *Please describe the procedure for adverse events (All Adverse Events must be reported as outlined in the SWT IRB policies and procedures)*

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# Part C: Recruitment of Participants

C1. Please include a summary to include:

1. participant inclusion/exclusion criteria;
2. recruitment methods;
3. Demographic information to be collected (i.e. gender, tribal affiliation, zip codes, etc.); and
4. any other information pertinent to your research study (use attachments if necessary to include recruitment flyers, focus group/interview guides)

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|  |

C2. Total number of participants you expect to enroll:

|  |
| --- |
|  |

C3. Incentives: Provide all compensation or credit offered to participants:

|  |
| --- |
|  |

C4. Are you including any special populations as identified in 45 CFR 46 (subpart B, C, D)?

YES  NO

If **yes**, please check which special population will be included:

Pregnant women or fetuses and neonates (45 CFR 46 Subpart B)

Prisoners (45 CFR 46 Subpart C)

Children (45 CFR 46 Subpart D)

C5. Please provide a description of any potential risks to research participants

|  |
| --- |
|  |

C6. Please provide a description of any potential benefits to research participants

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| --- |
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# Part D: Consent/Assent Forms

D1. Consent Form

“Consent” in this context means you are asking the subjects’ permission to be in your study, whether you ask via: 1) A HARD COPY SIGNED CONSENT FORM; 2) A VERBAL CONSENT TEXT THAT YOU READ TO THE PARTICIPANTS; OR 3) AN EMAIL INFORMATIONAL PAGE OR LETTER DESCRIBING THE STUDY.

**Choose ONE of the following 3 responses below** based upon 45 CFR 46 Sections 116 & 117:

I will obtain written informed consent from the participants and document their consent with a SIGNED consent form. **You must attach all copies of the consent form and/or assent form(s) addressing all the general requirements for informed consent [45 CFR 46.116(a)&(b)] For guidance refer to the *Southwest Tribal IRB Informed Consent Checklist for Investigators.***

I will obtain verbal informed consent from the subjects but am NOT obtaining written SIGNED consent as: (check all that apply): **You must attach a verbal script addressing the general requirements for informed consent [45 CFR 46.116(a)&(b)]**

The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; OR

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

I am asking for a waiver or alteration of the requirement to obtain informed consent. My project satisfies ALL four of the requirements of the four-part test in 46.116(d):

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practically be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

If you checked the above choice (#3), please complete (a) and (b):

a) Description of waiver or alteration:

|  |
| --- |
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b) Describe how the research project meets the four-part test:

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D2. Please describe how you will maintain confidentiality and anonymity of research participants.

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# Part E: IRB/Tribal Approval.

**E1. Does this study require IRB approval at other institution(s)? (Choose one):**

No, no other institutional IRB approvals or institutional permissions are required.

No, no other institutional IRB approvals are required, but an approval letter/MOU/MOA from participating tribal entity/Service Unit (Indian Health Service) is **attached**:

|  |  |
| --- | --- |
| Tribal entity/Service unit (IHS) | Date approved |
|  |  |

Yes and copies IRB approval from the following institution(s) are **attached**: (fill in)

|  |  |
| --- | --- |
| Institution Name | Date approved |
|  |  |

Yes, but IRB approvals from these other institutions are still pending: (fill in)

|  |  |
| --- | --- |
| Institution Name | Date submitted |
|  |  |

**E2. Tribal approval must be obtained from all tribes participating in the research project. Copies of Tribal approval letters must be included in the application.**

Does this research project involve the participation of tribal communities? (Choose one)

NO, there will be no tribal participation in the research study

YES, this research involves Tribal participation and Tribal approvals will be obtained. (COMPLETE TABLE BELOW):

Please list the names of the tribes who will be participating in the research study:

|  |  |  |
| --- | --- | --- |
| **1. Participating Tribe:** | | |
| Has approval been obtained? | YES | NO |
|  | If yes, provide date approval letter was obtained: | If no, provide date approval will be obtained by: |
| **2. Participating Tribe:** | | |
| Has approval been obtained? | YES | NO |
|  | If yes, provide date approval letter/resolution was obtained: | If no, provide date approval will be obtained by: |
| **3. Participating Tribe:** | | |
| Has approval been obtained? | YES | NO |
|  | If yes, provide date approval letter/resolution was obtained: | If no, provide date approval will be obtained by: |

# Part F: Dissemination

Please describe how you and your team intend to report results or progress for the research project according to anticipated project timeline. **Please include a copy of all abstracts, handouts, etc. (Please do not use N/A)**

**NOTE: All abstracts, presentations, and publications must be submitted to the Southwest Tribal IRB for pre-publication review and approval.**

F1. Dates and audience of presentations, reports, etc. to Tribal governments, Health Boards, lay groups, etc.

(add sheets if needed):

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| --- |
|  |

F2. Dates and audiences of all presentations, reports, newsletters, etc. to research participants or their families

(add sheets if needed):

|  |
| --- |
|  |

F3. Dates and audiences of all presentations, reports etc. to clinicians and caregivers

(add sheets if needed):

|  |
| --- |
|  |

F4. Dates and audiences of all presentations, reports, etc. to researchers or anyone else not mentions above (add sheets if needed):

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| --- |
|  |

F5. Dates and audiences of all publications to media outlets and/or social media (add sheets if needed):

|  |
| --- |
|  |

# Part G: Funding.

**Have you received any funding for this research project? No  Yes**

**Please provide information for all funding, awarded or proposed, in the past year related to this research project. Add additional sheets if needed. If research includes multiple funding, please copy and paste table for each funder and include information as requested. Include total amount for all funding directly below.**

**TOTAL FUNDING AMOUNT:**

|  |  |
| --- | --- |
| **Funding Awarded or Proposed** | |
| **Name of Principal Investigator:** |  |
| **Name of Funding Mechanism:** |  |
| **Name of Funding Agency:** |  |
| **Agency No. (if assigned)** |  |
| **Grant Number:** |  |
| **Title of Proposed Protocol** |  |
| **Anticipated Award Amount** |  |
| **Length of funding (years):** |  |
| **TOTAL:** |  |

**Part H: Principal Investigator Assurance: *Please read, select all boxes and sign below prior to submitting to the Southwest Tribal IRB***

|  |
| --- |
| **As Principal Investigator, I certify that:** |
| **I will protect the rights and welfare of all human participants.** |
| **Upon approval of this protocol, I agree to conduct this research as detailed in the protocol.** |
| **I will request and receive approval from the IRB for any alterations to the current protocol**  **prior to implementing changes.** |
| **I will comply with Federal and Southwest Tribal IRB policies for conducting ethical research**  **and I will be responsible for ensuring that my co-investigator(s)/student researcher(s)**  **comply with this protocol.** |
| **Any unexpected, adverse, or otherwise significant events in the course of this study will be**  **promptly reported to the Southwest Tribal IRB as stated in the Southwest Tribal IRB policies**  **& procedures.** |
| **I understand if the results of the research are used to prepare papers for publication or oral**  **presentations at professional conferences; manuscripts or abstracts must be submitted to**  **the Southwest Tribal IRB for pre-publication approval.** |
| **As Principal Investigator, I will abide by these *responsibilities.*** |

**Signature: \_\_\_\_\_\_\_\_\_\_ \_ \_\_** **\_\_\_\_\_\_ \_\_\_\_\_\_ Date: \_\_\_\_\_\_ \_**

Name of PI

Title of PI

**Signature:\_\_\_\_\_\_\_ \_\_\_\_\_\_ \_ \_\_** **\_\_\_\_ Date: \_\_\_ \_\_**

Name of Co-PI

Title of Co-PI

**Attachments:** Please paginate (consecutively after this application) and attach:

* Copy of your informed consent (If applicable) as indicated on page 5, section D1 (required);
* Citation list or bibliography (if needed) as stated on page 3, section B2;
* Project Timeline (required), survey or questionnaire, and additional documents (as needed) as stated on page 3, section B3;
* Budget
* CV’s or Resume of all Project Staff (required)
* CITI Training for key research personnel (required)
* All approval letters (IRB, Tribal, Institution), including MOU and MOAs (if applicable) are required as indicated on page 6.

Please note: If REQUIRED forms are not attached the application will be considered incomplete.