# Southwest Tribal Institutional Review Board

# RENEWAL/MODIFICATION APPLICATION

**Research Protocol No: \_\_\_\_\_ \_\_ \_ Renewal Due Date:**

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

**CHECK THE APPROPRIATE CHOICE: (Please type or print legibly)**

**To be RENEWED—NO CHANGES and have NOT STARTED PROJECT yet:**

Please complete all sections; sign and date assurance; return this Form.

**To be RENEWED with MINOR or NO CHANGES:**

Please complete all sections; sign and date assurance; return form with revised protocol [***with changes marked***] and **your most current consent document.**

**To be RENEWED with CHANGES in procedures, population, purpose, etc.:** Please complete all sections; sign and date assurance; return form with revised research protocol [***with changes marked***] and **your most current consent document.**

**MODIFICATIONS/CHANGES in procedures, population, purpose, etc.:** Please complete all sections; sign and date assurance; return form with revised research protocol [***with changes marked***] and **your most current consent document.**

**NOTE**: Changes to language in protocol or supporting documentation (informed consent forms, surveys, etc.) should be marked in brackets or text should be **bold** or *italicized*, or highlighted)**.** Also, **all sections must be completed or it will be considered incomplete.** Please ensure that all boxes are checked**.** If section is not applicable, please mark N/A (unless otherwise stated) and provide a statement why it is not applicable. **Paginate and label all appendices and attachments.**

One complete original SW Tribal IRB Application (signed) and 9 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**

# Part A: Contact Information for Research Team

**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 additional contact information for Research Personnel who will need to receive IRB Correspondence (copy and paste table below to add additional research personnel:**

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

**A2. Have there been any changes to personnel since last renewal?**

YES  NO

**A3. Please list other research personnel involved with the project: (i.e. co-PI, research assistant, field coordinators, etc.) Provide personnel name and 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: For new research team members, please include human protections training and Resume/CVs (no more than 5 pages).*

# Part B: Summary of Progress

**B1. Provide a summary of your progress to date: (add sheets if needed as attachment)**

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# Part C: Current Status of Human Research Participants:

**C1. Have participants been enrolled in the study?**

**YES  NO**

**If no, please state why:**

|  |
| --- |
|  |

**C2. If yes, please fill out participant enrollment table below:**

|  |  |
| --- | --- |
| **Participant enrollment** | |
| **Total number of participates enrolled to date:** |  |
| **Total number you project to enroll:** |  |

**Additional update regarding participant enrollment:**

|  |
| --- |
|  |

# Part D: Data and Safety Monitoring (\*for definitions please refer to the reporting procedures section in the Southwest Tribal IRB Policies & Procedures)

**D1. Provide a copy of your most current consent and/or assent documents. If the consent/assent form is not attached the application will be considered incomplete.**

**A copy of the most current consent form is attached to this application**

**The protocol was approved with an informed consent waiver (attach**

**approval letter)**

**Other:**

**D2. Were there any problems\* by participants or others involved in the study? No  Yes**

**If yes, Provide number and description of problems\* by participants or others (*include adverse event reporting form if submitted):***

|  |  |  |
| --- | --- | --- |
| **Number** | **Type (Complaints/problems)** | **Description** |
| 1 |  |  |
| 2 |  |  |

**D3. Was there any protocol and/or regulatory deviations or violations\* in the study? No  Yes**

**If yes, provide number, type and description of protocol and regulatory deviations or**

**Violations\*(*include adverse event reporting form if submitted):***

|  |  |  |
| --- | --- | --- |
| **Number** | **Type (protocol/regulatory deviation or violation)** | **Description** |
| 1 |  |  |
| 2 |  |  |

**D4. Were there any participants who withdrew or were discharged before they completed the study? No  Yes**

**Total number who withdrew or were discharged before they completed the protocol:**

|  |
| --- |
|  |

**Provide date and reason for each withdrawal or discharge (add sheets if needed):**

|  |  |
| --- | --- |
| **Date** | **Reason for withdraw/discharge** |
|  |  |
|  |  |

**D5. Were there any adverse events or harms in the study? No  Yes**

**If yes, provide number, type, and a brief description of adverse events\* (*include adverse event reporting form if submitted*):**

|  |  |  |
| --- | --- | --- |
| **Number** | **Type (Serious adverse event, expected serious adverse event, unexpected serious adverse event\*)** | **Description** |
| 1 |  |  |
| 2 |  |  |

**Describe how each adverse event/harm was handled (add sheets if needed):**

|  |  |
| --- | --- |
| **Adverse Event Number** | **How it was handled:** |
|  |  |

**D6. Were there any unanticipated benefits? No  Yes**

**If yes, provide number and description of unanticipated benefits (add sheets if**

**needed):**

|  |  |  |
| --- | --- | --- |
| **Number** | **Type of Unanticipated Benefit** | **Description** |
| 1 |  |  |
| 2 |  |  |

**D7. Were there any other unanticipated events? No  Yes**

**If yes, provide number and description of any other unanticipated event(s) (add sheets if needed):**

|  |  |  |
| --- | --- | --- |
| **Number** | **Type of Unanticipated Event** | **Description** |
| 1 |  |  |
| 2 |  |  |

# Part E: Findings

**E1. Summary of recent relevant literature or findings about research topic, including reports of multi-center trials, with particular attention to risks (attach citations/bibliography)**

|  |
| --- |
| **(add sheets if needed):** |

**E2. Brief summary of findings to date:**

|  |
| --- |
| **(add sheets if needed):** |

# Part F: How you and your team have reported results or progress of the research in the past year. Please include a copy of all abstracts, handouts, etc. (Do not use N/A – state if you will/will not report to these audiences and why)

**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):**

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| --- |
|  |

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

**(add sheets if needed):**

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| --- |
|  |

**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):**

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# Part G: Changes

**G1. Do you propose, or did you make any changes in this study or consent document:**

**No Yes (If yes, please describe below; add sheets if needed. Attach revised consent form with track changes)**

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| --- |
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# Part H: New Funding.

**Have you received any new funding? No  Yes**

**Have you applied for any new/additional funding? No  Yes**

**Please provide information for all additional funding, awarded or proposed, in the past year related to this research. Add additional sheets if needed.**

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

# Part I: 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 modifications 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)/research staff/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

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

Name of Co-PI

# Attachments:

Please attach a copy of your informed consent (if applicable) as indicated on page 2, section D1 and the citation list or bibliography (if needed) as stated on page 3, section E1. Please note: If the consent/assent form is not attached the application will be considered incomplete.