Southwest Tribal
Institutional Review Board (IRB)

Policies and Procedures

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APPENDICES

SOUTHWEST TRIBAL INSTITUTIONAL REVIEW BOARD (IRB)

The Southwest Tribal Institutional Review Board ("IRB") was created for the purpose of reviewing all proposals for health and health-related research conducted by the Albuquerque Area Indian Health Board, Inc. ("AAIHB"), the Albuquerque Area Southwest Tribal Epidemiology Center ("AASTEC"), and other projects involving Albuquerque Area tribes. The Southwest Tribal IRB is administratively assigned to the AAIHB for support services.

At the request of participating tribes or institutions doing research with these tribes, the Southwest Tribal IRB will review research proposals to assess the risks and benefits for research conducted in the Tribes and Tribal entities served by AAIHB and AASTEC. Each proposal is reviewed using criteria described in the Office for Human Research Protections (OHRP; formerly Office for Protection from Research Risk), Protection of Human Subjects, Title 45, Code of Federal Regulations (C.F.R.), Part 46, 1991. Research proposals are reviewed for safety, confidentiality (information about individuals is not released to anyone), degree of benefit, and the need for and quality of informed consent.

Much research has been done ethically and with great benefit to people before IRB's were mandated in 1981 in the USA. Some research has been unethical, that is, has harmed individual people or communities and/or has been less beneficial than it could have been. The purpose of all IRB's, including the Southwest Tribal IRB, is to help minimize harms to individuals and maximize benefits to society; insure that individuals are respected; and insure justice in research (The Belmont Report).

I. Federal Wide Assurance and the Federal Regulations

A. Federal Wide Assurance. Federal government agencies, such as the U.S. Department of Health and Human Services (HHS), require institutions and persons who apply for federal funding to conduct human subject research to sign an assurance that they will comply with federal human subject research regulations and requirements. The *"Federal Wide Assurance"* (FWA), which is approved by the Office for Human Research Protections (OHRP) at the Department of HHS, allows an IRB to approve federally funded research. The AAIHB (on behalf of the Southwest Tribal IRB) has been issued FWA #00010285, which sets forth a number of conditions. In this assurance, the Southwest Tribal IRB has agreed that it will apply these standards to all human subject research, whether or not it is federally funded.

B. Federal Regulations. Various federal regulations also contain requirements for the review and conduct of human subject research. Those regulations include 45 C.F.R. Part 46, entitled "*Protection of Human Research Subjects*" (HHS regulation), 21 C.F.R. Part 50, entitled "*Protection of Human Subjects*" (FDA regulation), and 21 C.F.R. Part 56, entitled *"Institutional Review Boards"* (FDA regulation). Other applicable FDA regulations, which the Southwest Tribal IRB and the investigator must follow, depending on the study, include 21 C.F.R. Part 312, *"Investigational Drugs"* and 21 C.F.R. Part 812, *"Investigational Devices."* In addition, the NIH and FDA disseminate guidelines for the conduct of certain types of research from time to time.

II. IRB Authority and Responsibility

In compliance with 45 C.F.R. Part 46 and 21 C.F.R. Part 50, the Southwest Tribal IRB is responsible for the following:

A. Review and Approve Research

1. The Southwest Tribal IRB shall have the responsibility to review, and the authority to approve or disapprove all research activities that use AAIHB or AASTEC funding and other projects submitted on behalf of Albuquerque Area tribes. The Southwest Tribal IRB shall be responsible for requiring necessary documentation on which to base their decisions.

2. If requested by tribes, the Southwest Tribal IRB will review research occurring in Indian communities that may use AAIHB or AASTEC facilities, data, staff, or funding, as a courtesy and will provide recommendations to the tribes regarding such research. All proposals for approval shall be complete. All such requests should have clear designation from tribal leadership either via resolution, letter of request or communication between the authorized tribal leadership and the Chair.

B. Suspend or Terminate Approval of Research. The Southwest Tribal IRB shall have the authority to suspend or terminate approval of research, as qualified above, that is not being conducted in accordance with IRB decisions, conditions, and requirements, or that has been associated with unexpected harms to subjects.

C. Imposed Condition and Requirements on the Duration of the Disapproval. Disapproval of an activity, termination or suspension of a previously approved activity or imposition of conditions or requirements for approval shall not be voided or modified by any other authority if the IRB actions were the result of a process fully in conformance with written IRB procedures.

III. Cultural Rights and Protections

The Southwest Tribal IRB respects the inherent sovereignty of all tribal entities. In this manner we provide secondary review to tribal entities. The Southwest Tribal IRB will review research projects using a culturally sensitive framework.

A. ***Privacy and Confidentiality:*** To honor tribal privacy and encourage confidentiality, the Southwest Tribal IRB prohibits investigators from authorizing the publication of the names of the tribal entities involved in the research project unless permission is granted by the tribe or as otherwise required by law.

B. ***Media release****:* all material released to the media or other social media outlets must receive prior approval from the tribal entity involved in research. This is to respect and recognize the authority of tribal entities to control the dissemination of their information.

IV. Policies and Procedures

A. Membership

1. *Appointment of Members*. The Southwest Tribal IRB will consist of 5-15 members. Appointments to the IRB shall conform to composition requirements (see Paragraph 5). Members who are Federal employees may serve on the committee as part of their duties. Community members and non-Federal employees will receive nominal payment for their services on this committee.

2. *Selection of Members.* In seeking members, the IRB coordinator works with the Southwest Tribal IRB and AAIHB to seek candidates for nomination considering the maintenance of diversity, gender representation and 45.CFR 46.107 requirements. When an appropriate candidate is found, an invitation letter is sent to the prospective candidate, inviting a response. If invitation is accepted, the formal appointment of new members is made by the IRB chair during an official IRB meeting.

3. *Term of Appointment*. The maximum term of appointment, including that of the Chair, shall be between three (3) to five (5) years. Appointments may be renewed upon recommendation of the Chair.

4. *Removal*. Any IRB member may be removed by the recommendation of the Chair for causes related to conduct, attendance, performance of assigned duties, or administrative activities. Members may not be removed solely on the basis of their opinions or decisions related to matters coming before the IRB. Appeal is limited to request for reconsideration addressed to the overall Board membership. The decision of the Board shall be final.

5. Emergencies. When a Chair is unable to be present due to a health, family or other emergency an IRB member will be elected to temporarily fulfill the Chair's responsibility. The elected member acts as Chair of the IRB, temporarily in the absence of the Chair, or should the Chair be unable or unwilling to perform their duties.

6. *Composition.*

   a. <u>Qualifications in General</u>. Members should possess a sincere interest in the activities of the IRB. The IRB as a whole should be comprised of

members with diverse backgrounds and should have the scientific, administrative, and cultural understanding necessary to review the research activities assigned to it and appropriate to the unique circumstances of the Albuquerque Area. IRB membership will consist of one member whose primary concerns are in scientific areas, one member whose primary concern is in the non-scientific area and one member who is not affiliated with the institution. (45 CFR 46.107)

b. Gender. There shall be male and female voting members.

c. Diversity. Members should represent a variety of professional disciplines related to the types of research coming before the IRB. At least one voting member shall possess primary expertise in a non-scientific area. At least 50% of the membership will be of American Indian and Alaska Native ancestry.

d. Community Representation. The IRB shall include at least one tribal/community member from the twenty-seven (27) tribal entities represented in the IHS Albuquerque Area.

e. Vulnerable Subjects. When research is reviewed dealing with a category of vulnerable subjects (e.g., prisoners, children, pregnant women, and mentally disabled people), the IRB shall include in its reviewing body one or more individuals who have, as a primary concern, the welfare of these subjects.

f. Physician Membership. There shall be at least one physician IRB member. A physician is defined as a primary health care worker.

7. *Vacancies.* Vacancies caused by resignation or departure of IRB members may be filled by a qualified alternate upon recommendation of the Chair. The appointment will be between three (3) to five (5) years for a staggered term. If the vacancy is not filled, the remaining members shall constitute the pool on which a quorum is based.

8. *Training*. IRB members participate in initial and continuing education by reviewing relevant materials on issues, regulation, and guidance concerning human subject's protection.

9. Initial/Orientation Training. New IRB members and staff are required to complete an orientation. This orientation will be conducted by IRB staff and introduce new members to the federal regulations (45.CFR.46 & 45.CFR.50), ethical guidelines (Belmont principles), Southwest Tribal IRB policies and procedures and their role and expectation as an IRB member. Additional relevant information to assist in the review process may be provided. New IRB

members and staff are required to endeavor to complete the Collaborative Institutional Training Initiative ["CITI"] training or equivalent.

10. Continuing Training. IRB members are required to maintain and provide current certification of completed CITI training or equivalent training. IRB members are also expected to stay up to date on current IRB related issues. Office for Human Research Protections (OHRP) trainings for members shall be provided with every member attending Public Responsibility In Medicine and Research (PRIM&R) at least once every three years subject to the availability of funds. Other supplemental human subjects protection training will be supported and encouraged (e.g., in-house training conducted by other Southwest Tribal IRB members for fellow board members and PRIM&R/OHRP Webinars).

6. *Members' Contributions to the IRB.*

    a. Regularly attend meetings and notify the IRB Coordinator of attendance at least one week in advance to obtain quorum.

    b. Receive and review application materials for proposed studies, requests for changes in protocol, continuing review updates, expedited reviews, adverse event reports, and other agenda items, including primary reviewer for a portion of newly proposed studies.

    c. Utilize one's community and professional expertise and judgment to actively review, participate in discussion of, and vote on all agenda items under consideration.

    d. Knowledgeable about the operating procedures of the IRB, federal regulations, and ethical guidelines under which the IRB oversees research involving human subjects/ participants.

    e. Serve as an expedited reviewer on appropriate minimal risk studies or minor changes in already Board approved research as requested by IRB staff or Chair.

    f. Participate in providing human subject protection training and outreach to researchers, tribal partners, and other IRB members as needed.

    g. Withdraw from service in the IRB when no longer interested or capable.

7. Members' Obligations to IRB, Research Participants and Researchers.

    a. Maintain confidentiality regarding IRB matters under consideration including: not divulging, publishing or otherwise making known to unauthorized persons, to third parties, or to the public any information obtained in the course of reading IRB materials or in the IRB meetings;

not using information obtained in the course of reading IRB materials or of the IRB meeting for other than official Southwest Tribal IRB purposes.

b. To help ensure unbiased IRB reviews, declare any conflict of interest by informing the IRB Chair and staff immediately if having a known or possible financial or any appearance of conflict of interest, associated with any research project under consideration at or before an IRB meeting. Chair will decide if the member will be recused.

B. Meetings

1. *Frequency*. Regularly scheduled IRB meetings will be held the first Thursday of every month; however, these meetings can be rescheduled at the discretion of the IRB Chair. Three members of the IRB may request a special meeting to be called, which will be promptly scheduled by the Chair.

2. *Quorum*. To take action on research a quorum shall include the majority of the current membership, including the Chair, one physician/scientist, and one voting member, whose primary concerns are in non-scientific areas. This quorum shall be present at the beginning and throughout the period of deliberation and decision-making.

3. *Decisions*. When a quorum is present and an issue presented, a majority of voting members is sufficient to decide. In cases where a consensus (unanimous) decision is not achieved, the minutes shall reflect the distribution of abstentions, favorable and unfavorable votes.

4. *Guests*.

   a. Consultants may be invited by the IRB Chair to be present at the meetings to provide analysis or summary of the technical or scientific aspects of the protocols. IRB members may ask questions to the Consultants for clarification.

   b. Investigators of research protocols being reviewed during the meeting may request an audience with the IRB. Investigators will only be called into the meeting to respond to questions by the IRB. Investigators must leave prior to IRB deliberations and decision making.

   c. Non-members of the IRB may be present at meetings with the permission of the IRB Chair and will be required to sign an IRB confidentiality agreement. Guests are not permitted to engage in discussion with the IRB or its members at meetings unless invited to do so by the Chair.

5. *Agenda*. The general agenda for scheduled IRB meetings is as follows:

a. Review of prior meeting minutes.

b. Presentation of expedited reviews.

c. Presentation of expedited approval modifications of existing studies.

d. Continuing review of existing studies (as applicable).

e. Review of newly proposed or resubmitted research (initial review).

f. Review of reports and abstracts for publication approval.

g. Additional reviews as requested by tribal communities or entities.

6. *Minutes.* The minutes of each meeting should contain at a minimum:

a. Quorum of voting members by name.

b. Guests present by name.

c. All actions taken by IRB.

d. Vote on actions that do not achieve consensus: those for, against, and abstaining.

e. Written summary of discussion.

f. Explanation of the basis for requiring changes or disapproving research.

g. Dissenting members' reports and opinions.

h. Record of IRB members' conflict of interest with statement that this member did not participate in the review except to provide requested information.

i. Scheduled date and location for next meeting, if known.

j. Starting and ending time of meeting.

k. Minutes or portions thereof may be provided to non-members only by written request and approval by the Board at a duly called meeting with a quorum present. If the matter is approved, confidentiality agreement shall be signed by the requestor.

l. Formal acceptance of minutes.

C. Types of Review: Southwest Tribal IRB review is required when a study meets the criteria as defined by the federal regulations as human subject's research (45.CFR.46.101). At this point the Southwest Tribal IRB is not reviewing Federal Drug Administration (FDA)(21. CFR .56) research protocols.

1. ***Full Review.*** Accomplished through a formal meeting of the IRB that has a quorum through the final decision. The researcher(s), IRB member(s), with a conflict-of-interest, and any public person may attend the initial discussion in the "open meeting" phase of the review. Once this phase that includes questions to the researcher(s) is finished, all individuals with a conflict of interest must leave for the closed meeting phase of discussion and IRB decision. The public must also leave before the closed meeting begins, unless permitted to stay by the Chair. The criteria for a full IRB review must meet and may exceed all regulatory criteria. The regulatory criteria are outlined in 45 C.F.R. 46 Subparts A-D (see appendices). The procedures for a full review in the open meeting phase include:

    a. Outlining the protocol (by researcher, if present or IRB member) to include purpose or aims, methods, and procedures.

    b. All IRB members may ask questions of the researcher(s) present and others.

    c. The Chair, members knowledgeable about one or another aspect of the protocol, researcher(s) and guests may explain technical details.

    d. The procedures for a full review in the closed meeting phase (to minimize any possible external pressure on any IRB member for or against the decision) include:

        i. Further discussion if needed.
        ii. ii. The Chair will ask for a decision. In general, the IRB should strive to achieve a consensus and also incorporate as many final concerns, answers, conditions and suggestions offered by individual IRB members taking into consideration recommendations provided by community IRB members who are enrolled tribal members.

    e. Decisions the IRB may make in full review:

        i. Approve the protocol as proposed with no changes; or
        ii. Approve the protocol, but WITH CONDITIONS, related to human research protection issues that the researcher must change before final approval; or

iii. Defer final review of the protocol, either pending receipt of more information from the researcher or pending required major changes and resubmission;
iv. Disapprove the protocol. Disapproval is not decided on the initial review. The Southwest Tribal IRB "defers" the protocol on its initial review, and sends a deferral letter to the Principal Investigator explaining what should be done to make the protocol acceptable.

f. Additional decisions: If the IRB approves a protocol (with or without conditions) the IRB must then decide:

i. If the approval requires changes to meet certain conditions, whether to verify that the conditions are met can be done by the expedited review procedure; and
ii. Whether the protocol is "not greater than minimal risk;" and
iii. The frequency to conduct periodic review; and
iv. The level of the next or interval reviews of the protocol (i.e. whether by full review or expedited review).

2. ***Expedited Review:*** May be conducted for annual reviews, amendments, project materials, abstracts, presentations, publications and final reviews. In general, expedited reviews are conducted by the Chair and another member of the IRB or the Primary Reviewer.

i. Frequency: as required, outside of full board meetings.

ii. Reviewers: One regular member, serving as a Primary Reviewer, and the Chair; or two regular members of which one is serving as Primary Reviewer.

iii. Decisions: Reviewers shall form a consensus. If a consensus cannot be reached, the review may be brought before the full board. A reviewer may at any time determine that the review should be conducted by the full board. A summary of the reviews shall be presented to the full board, and at any time one or more IRB members may request that it be reviewed by the full board. Southwest Tribal IRB members will be informed of all final decisions made via expedited review at the monthly IRB meetings.

D. Correspondence with Principal Investigators. All official correspondence with investigators shall be made in writing, incorporating the concerns and decisions of the IRB. Written or oral correspondence must be sent to the IRB Coordinator who will forward all communication to Southwest Tribal IRB chair.

V. Submitting Materials

The Southwest Tribal IRB reviews research proposals, annual progress reports, and papers being submitted for publication along with abstracts for conference presentations.

A. Research Proposals. All new applicants must complete a new application and/or submit their research proposal. One complete application and eight copies must be submitted no later than the protocol submission due date to the Southwest Tribal IRB Coordinator. The due date can be found on the Southwest Tribal IRB Meeting Schedule. Research proposals and new applications must contain the following items to be considered complete:

1. A clear and complete description of the research to be conducted.
2. A copy of the consent form.
3. Information on the consent process.
4. If applicable, a copy of the assent form.
5. If applicable, information on the assent process.
6. 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.
7. If applicable, a copy of the Indian Health Service Area or Service Unit approval letter.
8. A copy of the tribal approval letter from each participating tribe.
9. A copy of the proposed procedures to maintain confidentiality and anonymity.
10. If the proposal includes a survey or questionnaire, copies need to be submitted.
11. Curriculum vitae (CV) or resumes of all project staff.
12. Budget.
13. Timeline.
14. Proof of human subjects' protection training completion for key research personnel including those working directly with the community.
15. Procedure for reporting adverse events.
16. Funding source(s) disclosure.

17. Signed principal investigator assurance

B. Status Report and Renewal Application. Status reports and renewal applications are required at one-year intervals from the date of initial review or more frequently as may be required by the IRB. The IRB will send an annual renewal application to the Principal Investigator one month before the anniversary date. If there are changes to be made during the year of Southwest Tribal IRB approval, a status report and renewal application must be complete documenting the changes. If major changes are to be made, a copy of the revised protocol must also be submitted. A status report and renewal application is considered complete when the investigators provides the following:

1. Specification as to whether or not there have been changes to the study protocol since the date of last review.

2. Specification as to whether the research project has been completed since the date of last review.

3. Summary of progress

4. Current status of human research participants

5. Data and Safety Monitoring

6. Findings

7. Reported results of progress within the past year

8. Description of changes (if applicable)

9. New funding

10. Signed principal investigator assurance

C. Publications/Presentations. All abstracts, publications and presentations require Southwest Tribal IRB approval prior to implementation. A complete *Abstract, Publications, Presentation* (APP) form must be completed for IRB review. An APP form is considered complete when the investigator(s) provides the following:

1. Review request

2. Disclosure of previous IRB approval

3. A copy of the tribal approval letter.

4. The name of the journal the article will appear in or title of conference.

5. Anticipated date for submission of publication or conference abstract/poster/presentation.

6. A copy of the manuscript, abstract, and/or presentation including authors, title, abstract¸ article, and references.

7. Signed Principal Investigator Responsibilities.

D. Closure or withdraw of research.

1. Project Closure. Research approved by the Southwest Tribal IRB expires one year from the approval date. Before the end of the approval date the project must either:
    a. officially close prior to or at the end of the date of expiration; or
    b. Receive continuing review and approval prior to the expiration date.

    The PI and/or the IRB may close approved projects. Procedures for closing a study fall into five categories:
        i. Closure due to receipt of final status report
        ii. Closure after expired approval – IRB approval has lapsed over 30 days and PI is in the process of submission.
        iii. Closure after expired approval and PI's non-response to requests for closure report or renewal application.
        iv. Closure due to PI's non-response to IRB (6 months from last board decision letter)
        v. Withdraw request initiated by PI
2. For a lapsed protocol, PI must submit a closure form and a renewal form
3. To close or withdraw a project, the PI must submit a closure form
4. If approved for closure or withdraw an official letter documenting this decision will be sent to the principal investigator. A lapsed protocol can be renewed and approval letter will be sent to the principal investigator.

VI. Records

A. The IRB shall maintain the following records for a minimum of five (5) years after the conclusion of the last IRB approval period for the activity: copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposal, approved sample consent documents, progress reports submitted by research investigators, and reports of adverse events to subjects, minutes of IRB meetings, minutes of continuing review activities, and copies of all correspondence between the IRB and the research investigators.

B. At the end of the five-year period, records will be disposed and IRB will get a certificate of destruction.

VII. Reporting Procedures

The Southwest Tribal IRB shall promptly report information to the Tribe/Tribal entity and the Office of Human Research Protections (OHRP). Investigators are required to use the Southwest Tribal IRB reporting form. The IRB shall follow the procedures outlined below**:**

A. Regarding Individual Research Protocols (Compliance Problems, Deviations, Violations and Events Encountered During the Provision of Research)

i. ***Problems:*** The Southwest Tribal IRB considers "Problems" to be events likely related to the research that are less than serious, and may be Expected or Unexpected. Problems are minor disturbances in one (1) or more of the six (6) types of harms, or in privacy, that are not likely to be a permanent or long-term worsening of the participant's/subject's or community's status in the harm(s) or privacy.

a. An example of a Problem in research could be when a participant being interviewed about an emotionally-laden topic becomes quite emotional and tearful. The research expected that this might happen to a small number of people being interviewed, and has an appropriate plan in place to manage such a situation. The Investigator checks with the participant the next day and determines that the person has no residual problem resulting from the interview.

b. The Investigator should report Problems to the Southwest Tribal IRB **within 15 working days** of the event. The IRB will track the number of Problems associated with a protocol to determine if the protocol or consent document should be changed.

ii. ***Protocol and Regulatory Deviations or Violations*****:** Protocol and Regulatory Deviations or Violations are any actions or events that are not in accordance with the approved protocol, IRB policies, federal regulations or IRB determinations.

a. *Protocol and Regulatory Deviations*: Protocol deviations are actions or events that occur outside of the protocol and/or the approval requirements and that have little or no chance of disturbing harm to participants/subjects, the Tribe or the community.

b. Examples of protocol or regulatory deviations may include:

- Delaying an interview with a subject one (1) or two (2) days after the last scheduled date of interviews due to inclement weather, to ensure the safety of the subject;
- The Tribal Council postpones the scheduled semi-annual report by the Investigator for a period of time;
- Failure to send the Southwest Tribal IRB the tribal council's signed resolution approving research activities in the tribal community; or
- A lapse of one (1) week or less in the approval renewal for a project that has not yet started research activities involving human participants/subjects.

c. Investigators must report protocol deviations to the Southwest Tribal IRB **within 15 working days** of noting the deviation.

d. The Southwest Tribal IRB may:

i. Accept the deviation as beyond the control of the Investigator, or

ii. May work with the Investigator and/or the Investigator's supervisor to avoid a similar deviation in the future.

iii. ***Protocol and Regulatory Violations*****:** Protocol and Regulatory violations are actions or events that occur outside of the protocol and/or the approval requirements but have had or may have the chance of a **significant harm** to human participants/subjects, the Tribe or the community.

a. Examples of protocol and regulatory violations may include:
   - A letter sent to the wrong address or person that contains sensitive information about illegal behavior by an identified other person;
   - Advertent or inadvertent disclosure of Tribal-specific data or analysis in research in which participating tribes were to remain unidentified and that contained potentially stigmatizing or other harmful information;
   - Failure to obtain tribal council approval as required by the IRB; or
   - A lapse of one (1) month in the approval renewal for a project involving human subject research participants with no evidence that the Investigator is trying to comply quickly.

b. Investigators must report protocol violations **within five (5) working days** of noting the violation.

B. The Southwest Tribal IRB will handle Protocol and Regulatory Violations as Unexpected Serious Adverse Events, below.

1. Serious Adverse Events

Serious Adverse events are those which occur during the course of a research protocol that cause serious harm, increase the chance of serious harm, or result in a serious loss of privacy of an individual human or community participant/subject or others (such as family members). The Southwest Tribal IRB considers harm to include physical, psychological, social, economic, legal, dignitary or privacy. The IRB considers a "serious" event to be one that produces, or has the chance of producing, a harm that will be long-term or permanent, significantly lowering a participant's/subject's physical, psychological, social, economic, legal, or dignitary status or infringing on their privacy.

2. **Expected Serious Adverse Events**

Expected Serious Adverse Events are serious events that are reasonably expected and are listed in both the protocol and the consent form as a serious risk of participating in the research. An example would be participant/subject death or disability in a clinical trial of a new treatment for a condition that itself causes death or disability using the current treatments.

a) The Southwest Tribal IRB requires Investigators to report expected serious adverse events as they occur, in order for the IRB to track the severity and number of expected serious adverse events.

b) At the time of intial and annual renewal, Investigators must report the total number and brief description of each type of expected serious adverse event that occurred since the last Renewal and for the total project period.

3. **Unexpected Serious Adverse Events**

Unexpected Serious Adverse Events are serious events that were not expected, and were not listed in the protocol or consent form as an expected additional serious risk of participating in the research.

i. Examples of Unanticipated Serious Adverse Events include:
    - Theft, loss, or other security breach of study data;
    - Unexpected release of sensitive information about the Tribe or community;
    - Unexpected human subject suicidal ideation;
    - Unexpected enrollment of a member of a federally-protected population as defined in 45 CFR Part 46 (prisoners, pregnant women, fetuses and children); or
    - Death of a participant/subject in which occasional death is unexpected.

ii. If the Unexpected Serious Adverse Event is the **death** of a human participant/subject, Investigators must contact the Southwest Tribal IRB and all other IRBs that have oversight of the research within 24 hours. **[45 CFR Part 46.103(b)(5)]**

iii. Failure to contact the Southwest Tribal IRB within the required time may result in further actions by the IRB.

iv. Depending on the nature of the Event, the IRB may send preliminary information **within 24 hours** of learning of the Event to the:
    1) Investigator's host institution's Institutional Official
    2) Investigator's host institution's office sponsoring the research project
    3) Officials or representatives of participating tribes or tribal organizations
    4) Office of Human Research Protections (OHRP)
    5) Project Officer and/or grants manager of the funding agency
    6) Other federal agencies as required, and
    7) All other IRBs or entities that have oversight of or responsibility for the research. **[45 CFR Part 46.103(b)(5)]**

v. For all other Unexpected Serious Adverse Events, Investigators must contact the Southwest Tribal IRB and all other IRBs that have oversight of the research **within five (5) working days** of learning of the Event. **[45 CFR Part 46.103(b)(5)]**

vi. After being informed of an Unexpected Serious Adverse Event, the IRB will re-examine the balance of risks or harms compared to benefits for human participants/subjects, and may:
    a. Ask for more information from the Investigator;
    b. Require changes in the research procedures and activities to minimize the adverse events;
    c. Require that the informed consent process and the consent documents for individual participants/subjects describing the risks be appropriately revised before further research activities take place;

d. Require that participants/subjects already enrolled in the research be properly informed; and
e. Require that consent documents for communities already participating be informed before further research activities take place.

C. Suspension or Termination of Southwest Tribal IRB Approval of Research

1. The Southwest Tribal IRB has the authority to suspend or terminate approval of an active research project if:
    a. The research is not being conducted in accordance with the Southwest Tribal IRB decisions, conditions and/or requirements; or
    b. The research has been associated with unexpected serious harm to participants/subjects.

D. Immediate Suspension

1) The IRB Chair may immediately temporarily suspend all or some research activities of a research protect upon obtaining information about a serious breach of human research protection regulations or procedures, especially a breach that poses one (1) or more serious potential harms to individuals or to tribes/communities. The serious potential harm may be physical, psychological, social, economic, and legal or dignitary. Another type of serious potential harm involves breaks of private information about participants/subjects or of confidentiality by the project. **[45 CFR Part 46.111(a)(7)]**
2) The Southwest Tribal IRB will notify the researcher, the researcher's primary IRB, OHRP, the Chair(s) and the Tribe(s) involved.
3) As soon as is practicable after the immediate temporary suspension, the IRB Chair with or without additional people authorized by the Southwest Tribal IRB, will meet with the researcher, research staff, complainants (if any), and other appropriate people, to discover the full facts of the situation. The IRB Chair should continue to consult with the researcher, researcher's home IRB, OHRP, and attorney. The Tribe(s) involved in the research will be partners in determining the course of future action, which may include remedial components. Full due process will continue to be maintained. The full IRB and the involved Tribe(s) must review and approve the proposed final resolution. The Southwest Tribal IRB will notify the researcher, the researcher's home IRB, OHRP, the Chair(s) of the Tribe(s) involved in writing about the final resolution. **[45 CFR Part 46.113]**
    a) The decision to **permanently** suspend or terminate research activities must be made by the full IRB board.
    b) Regulatory resource documents for Suspension, Termination and non-termination resolution of a research project include:
        i) 45 CFR 45.116;
        ii) OHRP's "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events," can be found at http://www.hhs.gov/ohrp/policy/advevntguid.html.
        iii) OHRP's "Guidance on Reporting Incidents to OHRP" can be found at http://www.hhs.gov/ohrp/compliance/reports/index.html.

4) Imposed Conditions and Requirements on the Duration of Disapproval. An outside authority may not void or modify any IRB
    a) Disapproval of research activity;
    b) Termination or suspension of previously-approved activities; or
    c) Imposition of conditions or requirements for approval if the actions of the IRB were the result of a process fully in conformance with written IRB procedures.
5) Procedures to Report Termination of Southwest Tribal IRB Approval of Research
    a) If the IRB protocol approval is suspended or terminated, the Southwest Tribal IRB is required to report **within five [5] working days** to the following officials and institutions:
        i. Southwest Tribal Institutional official
        ii. Investigator's host institution's Institutional official
        iii. Investigator's host institution's Office of Sponsored Programs
        iv. Officials or representatives of participating tribes or tribal organizations
        v. Office of Human Research Protections (OHRP)
        vi. Project Officer and/or grants manager of the funding agency
        vii. Other federal agencies as required, and
        viii. All other IRBs or entities that have oversight of or responsibility for the research. **[45 CFR Part 46.103(b)(5)]**

E. Regarding IRB Proceedings and Procedures. IRB correspondence containing a summary of results of IRB deliberations as they pertain to a particular tribe shall be promptly sent to the tribe or tribal entity.

VIII. Student IRB Support

The Southwest Tribal IRB is committed to assisting Native American students in learning, understanding, and navigating the IRB process. Members of the IRB will fill the role of mentor and advisor to students in need of this service.

IX. Fee Schedule

The Southwest Tribal IRB will charge for-profit and non-profit entities, and State, Federal, Tribal, and University institutions for review of their protocols irrespective of the number of Albuquerque Area tribes involved in the project, at the discretion of the IRB. Fee waivers will be decided on a case-by-case basis. The fee schedule will be as follows:

A. $1,200 for full committee review.

B. $500 for IRB comment and review.

C. $250 for continuing or expedited review.

X. Point of Contact

Southwest Tribal Institutional Review Board
c/o Albuquerque Area Indian Health Board, Inc.
Attn: Rachell Tenorio, Southwest Tribal IRB Coordinator
5015 Prospect Avenue NE
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