Seneca Nation Health Board (SNHB)

Research Review Committee (RRC)

Policy and Procedures

(Effective June 12, 2021)

Office of the Seneca Nation Health System CEO
Lionel R. John Health Center
987 RC Hoag Drive
Salamanca, NY 14779

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SECTION I. INTRODUCTION TO SENECA NATION RESEARCH POLICY AND RELEVANT FEDERAL REGULATIONS

A. Seneca Nation Research Policy. All persons within the territorial jurisdiction of the Seneca Nation (hereinafter, "Nation") are free from harmful, intrusive, ill-conceived or otherwise offensive research, investigative procedures, or misuse or misappropriation of research findings and biological and genetic materials. Research must be deemed as beneficial. community-based, culturally relevant and protective, and consistent with Nation health priorities and concerns. The Nation, being sovereign, has the right of self-determination and in exercising that right must be recognized as the exclusive owner of indigenous traditional knowledge, data products, and all genetic and biological materials associated with a Nation approved investigation. Any research information and all biological material and data generated by and about Nation individuals, communities and culture represent the inalienable intellectual properties of the Nation and over which the Nation provides oversight. Nation Research Policies and Procedures are a mechanism to inform relations between the Nation and researchers and staff; to promote collaboration within a framework of mutual respect, equity, and empowerment; and to identify the potential benefits and risks to the Nation, its Peoples, and its resources. See Seneca Nation Research Policy (Appendix B).

SECTION II. SENECA NATION HEALTH BOARD RESEARCH REVIEW COMMITTEE ("SNHB RRC" OR "RRC") AUTHORITY AND RESPONSIBILITY

The SNHB RRC is responsible for the following:

A. Review and Recommend Approval of Research

The SNHB RRC shall have the responsibility to review, and the authority to recommend to Nation Council (hereinafter, "Council") approval or disapproval of all research activities that use Nation resources and/or that occur within Nation jurisdiction. The SNHB RRC shall be responsible for requiring necessary documentation on which to base their decisions.

- B. Suspend or Terminate Approval of Research. The SNHB RRC shall have the authority to request the Council to suspend or terminate approval of research, as qualified above, that is not being conducted in accordance with RRC decisions, conditions, and requirements, or that has been associated with unexpected harms to participants, community, or culture.
- 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 authority other than the Council.

SECTION III. CULTURAL RIGHTS AND PROTECTIONS

The RRC upholds the sovereignty of the Nation. In this manner, RRC provides secondary review to Council. The RRC will review research protocols using a cultural enrichment and protections orientation.

- A. *Privacy and Confidentiality:* To honor Nation privacy, sacred cultural practices and resources, and encourage confidentiality, the RRC prohibits investigators from authorizing the publication of the name of the Nation unless permission is granted by Council.
- B. *Data Sovereignty:* Data of any type collected for a Nation-approved study inherently belongs to the Nation. This is to respect and recognize the authority of the Nation to control the dissemination of their information.
 - a. *Media release*: all material released to the media or other social media outlets must receive prior approval from the RRC and the Council.
 - b. *Publication release:* Investigators who intend on publishing collections of materials and/or data in print or in any digital form must formally notify the RRC. All research data released for publications must be provided to the RRC for recommendation to Council for final determination, prior to release of data.

SECTION IV. POLICIES AND PROCEDURES

A. Membership

- 1. Appointment of Members. The SNHB RRC will consist of 5 members. Appointments to the RRC shall conform to composition requirements (see Paragraph 6). Committee members who are not employees of the Nation will be eligible to receive a stipend for their services in the amount of \$200.00 per month for each month where they attend a meeting where a quorum is present. [Note: Meetings shall be called as needed and it is possible that meetings may not occur on a monthly basis. See Section IV(B)(1)]. All members of the SNHB RRC shall be entitled to reasonable expenses associated with committee membership, including mileage.
- 2 Selection of Members. Upon the recommendation of candidates by the Health Board, Council shall select and appoint the Seneca Nation Health Board members of the SNHB RRC and the Seneca Nation Health System Leadership member of the SNHB RRC. The Nation's Clerk shall advertise for Community members of the SNHB RRC and shall forward letters of intent and résumés to the Health Board for review of the materials. The Health Board shall then forward recommendations to Council who shall

- select and appoint the community members. The selection of SNHB RRC members shall conform to composition requirements found in Paragraph 6.
- 3. Term of Appointment. Terms of the Seneca Nation Health Board members serving on the SNHB RRC shall coincide with their terms on the Seneca Nation Health Board. The term for the Seneca Nation Health System Leadership member of the SNHB RRC shall be for three (3) years. The appointment may be renewed upon recommendation of the Chair to Council. Otherwise, the Chief Operations Officer shall serve after the Chief Executive Officer, or vice versa. The terms of the Community members shall be for three (3) years. Appointments of Community members may be renewed upon the recommendation of the Chair to Council.
- 4. Removal. Any RRC member may be removed by the recommendation of the Chair to Council 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 RRC. Appeal is limited to request for reconsideration addressed to the overall RRC membership. The RRC Chair will communicate results of the appeal with a recommendation to Council. The decision of Council shall be final.
- 5. *Emergencies*. When the Chair is unable to be present due to a health, family or other emergency an RRC member will be elected to temporarily fulfill the Chair's responsibility. The elected member acts as Chair of the RRC, temporarily in the absence of the Chair, or should the Chair be unable or unwilling to perform their duties.

6. Composition.

- a. Qualifications in General. Members should possess a sincere interest in the activities of the RRC. The RRC as a whole should be comprised of members with diverse backgrounds and should have the scientific, policymaking, health or medical, and cultural understanding necessary to review the research activities assigned to it and appropriate to the unique circumstances of the Seneca Nation.
- b. <u>Seneca Nation Health Board Membership</u>. There shall be 2 SNHB RRC members, one of whom will serve as RRC Chair.
- d. <u>Seneca Nation Health System Leadership</u>. There shall be 1 SNHS RRC member who is either the Chief Executive Officer or the Chief Operations Officer.
- e. <u>Community Representation</u>. The RRC shall include 2 community members, one each from Allegany and Cattaraugus Territories, who are recognized for their community enhancement activities and/or for their work in cultural preservation, practices, or enrichment.
- g. <u>Subject Matter Experts (non-voting)</u>. When research is reviewed dealing with a category of vulnerable subjects (e.g., prisoners, children, pregnant women, and mentally disabled people), the RRC shall include in its reviewing body one or more

individuals who have, as a primary concern, the welfare of these subjects. Other subject matter experts could include persons with relevant credentials in fields such as genetics/genomics, randomized controlled trials, clinical trials, research methods not commonly used, and other issues being proposed that are outside the areas of expertise of the voting RRC members. Subject Matter Experts are advisory to the RRC providing one-time or recurring expert advice.

- 7. Vacancies. RRC members shall serve until their successor is duly appointed, or until their death, resignation or removal by Council. Vacancies on the RRC shall be filled by the Council, upon the recommendation of the Seneca Nation Health Board, and the appointment will be for the unexpired remainder of that position's term.
- 8. *Training*. RRC members participate in initial and continuing education by reviewing materials relevant to Nation needs, and issues, regulation, and guidance concerning human subject's protection.
- 9. Initial/Orientation Training. New RRC members will complete an orientation based on the Research Ethics Training for Health in Indigenous Communities (rETHICS) curriculum. The RRC Chair and/or consultants will conduct this orientation. Additional training materials will include relevant regulations ethical guidelines, e.g., Belmont principles; the SNHB RRC policies and procedures; and will review the role and expectations of an RRC member. Additional relevant information to assist in mastery of the research review process may be provided.
- 10. *Continuing Training*. As RRC member training needs are identified, the RRC Chair will arrange training to meet those needs and will offer at least annual refresher or updated training.

11. Members' Contributions to the RRC.

- a. Regularly attend meetings and notify the RRC Chair of attendance at least one week in advance to obtain quorum. If an RRC member is not in attendance for three consecutive meetings without notification of absence, RRC membership will be re- evaluated for that RRC member.
- 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 RRC, Nation research policy, federal regulations, and ethical guidelines under which the RRC oversees research involving Nation participants.

- e. Serve as an expedited reviewer on appropriate minimal risk studies or minor changes in already Board approved research as requested by RRC Chair.
- f. Withdraw from service in the RRC when no longer interested or able.

12. Members' Obligations to RRC, Research Participants and Researchers.

- a. Maintain confidentiality regarding RRC 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 RRC materials or in the RRC meetings; not using information obtained in the course of reading RRC materials or of the RRC meeting for other than official SNHB RRC purposes.
- b. To help ensure unbiased RRC reviews, declare any conflict of interest by informing the RRC Chair immediately if having a known or possible financial interest or any appearance of a conflict of interest, associated with any research project under consideration at or before an RRC meeting. Chair will decide if the member will be recused. Persons employed by or associated with universities or institutions that regularly engage in research activities that use Nation resources and/or that occur within Nation jurisdiction shall be prohibited from serving on the SNHB RRC.

B. Meetings

- 1) *Frequency*. The RRC Chair shall call meetings as needed. Additionally, actions may be taken through Action by Written Consent (See Section IV (B)(7), *Action by Written Consent*)
- 2) **Quorum.** To take action on research a quorum shall include the majority of the current membership, including the Chair. 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. In cases of a tie vote, the motion fails.

4) Guests.

- i. Consultants may be invited by the RRC Chair to be present at the meetings to provide analysis or summary of the technical or scientific aspects of the protocols. RRC members may ask questions to the Consultants for clarification.
- ii. Investigators of research protocols being reviewed during the meeting may request an audience with the RRC. Investigators will only be called into the meeting to respond to questions by the RRC. Investigators must leave prior to RRC deliberations and decision making.
- 5) Agenda. The general agenda for scheduled RRC meetings should include the

following topics:

- i. Review of prior meeting minutes.
- ii. Presentation of expedited reviews.
- iii. Presentation of expedited approval modifications of existing studies.
- iv. Continuing review of existing studies (as applicable).
- v. Review of newly proposed or resubmitted research (initial review).
- vi. Review of reports and abstracts for publication approval.
- vii. Additional reviews as requested by tribal communities or entities.
- 6) Minutes. The minutes of each meeting should contain:
 - i. Quorum of voting members by name.
 - ii. Guests present by name.
 - iii. All actions taken by RRC.
 - iv. Vote on actions that do not achieve consensus: those for, against, and abstaining.
 - v. Written summary of discussion.
 - vi. Explanation of the basis for requiring changes or disapproving research.
 - vii. Dissenting members' reports and opinions.
 - viii. Record of RRC members' conflict of interest with statement that this member did not participate in the review except to provide requested information.
 - ix. Scheduled date and location for next meeting, if known.
 - x. Starting and ending time of meeting.
 - xi. Minutes or portions thereof may be provided to non-members only by written request and approval by the RRC Chair. If the matter is approved, confidentiality agreement shall be signed by the requestor.
 - xii. Formal acceptance of minutes and approval to submit to the SNHB.

- 7) Action by Written Consent. The RRC may take any and all actions which are required or permitted concerning the conduct of the business of the RRC without a meeting if all of the RRC members consent in writing to the adoption of resolutions authorizing the action. Email communications may be considered a writing for the purposes of this provision. Such resolutions and such written consents shall be filed with the minutes of the next meeting of the RRC.
- C. Review Requirement: SNHB RRC review is required when a study meets the criteria as defined by the federal regulations as human subjects research (45 CFR 46.101). Generally, applicants must submit evidence of prior approval from an institutional research review entity such as an Institutional Review Board (IRB) before the SNHB RRC shall review a study. The institutional research review entity should abide by various federal regulations containing requirements for the review and conduct of human subject research. These regulations include 45 C.F.R. Part 46, "Protection of Human Research Subjects" (HHS regulation); 21 C.F.R. Part 50, "Protection of Human Subjects" (FDA regulation); and 21 C.F.R. Part 56, "Institutional Review Boards" (FDA regulation). Other applicable FDA regulations, which 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.

An applicant lacking prior approval from an institutional research review entity may submit a waiver request to the SNHB RRC and the RRC shall make a discretionary determination on whether approval of the waiver request is warranted.

Types of Review:

- 1. *Full Review.* Accomplished through a formal meeting of the RRC that has a quorum through the final decision. The researcher(s), RRC 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 RRC decision. The public must also leave before the closed meeting begins, unless permitted to stay by the Chair. The criteria for a full RRC review must meet and may exceed all regulatory criteria. The regulatory criteria are outlined in 45 CFR, 46 Subparts A-D. The procedures for a full review in the open meeting phase include:
 - a. Outlining the protocol (by researcher, if present or RRC member) to include purpose or aims, methods, and procedures.
 - b. All RRC 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 RRC member for or against the decision) include:
 - i. Further discussion if needed.
 - ii. The Chair will ask for a decision. In general, the RRC should strive to achieve a consensus and also incorporate as many final concerns, answers, conditions and suggestions offered by individual RRC members.
- e. Decisions the RRC 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. Approve the protocol WITH RECOMMENDATIONS, related to the human research protection. No need to resubmit.
 - iv. Defer final review of the protocol, either pending receipt of more information from the researcher or pending required major changes and resubmission;
 - v. Disapprove the protocol. Disapproval is not decided on the initial review. The SNHB RRC "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.
- 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 RRC or the Primary Reviewer(s) if assigned.
 - a. Frequency: as required, outside of full board meetings.
 - b. Reviewers: RRC member serving as a Primary Reviewer, and the Chair; or two regular members of which one is serving as Primary Reviewer (if assigned).
 - c. 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 RRC members may request that it be reviewed by the full board. SNHB RRC members will be informed of all final decisions made via expedited review at the monthly RRC meetings.
- 3. **Exempt.** Must meet four requirements:
 - a. The research involves no more than minimal risk to the subjects;
 - b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - c. The research could not practicably be carried out without the waiver or alteration;
 - d. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

SECTION V. SUBMITTING MATERIALS

The SNHB RRC reviews all new research proposals, annual progress reports (renewals; also known as continuing review), modification applications, papers being submitted for publication along with abstracts for conference presentations, adverse events reports and closure reports submitted. These documents will be mailed to RRC members a week prior to each meeting.

- A. New Applications or Research Proposals. Applicants must complete a new application and/or submit their research proposal. RRC members are encouraged to use the SNHB RRC Checklist for reviewing the new research proposal. Research proposals and new applications must contain the following items to be considered complete:
 - 1. Signed Cover Letter
 - 2. Research Proposal Submittal Checklist
 - 3. Complete New Application:
 - a. Contact Information for the primary and/or secondary contact of the research project.
 - b. Research Description with a clear and complete description of the research to be conducted, participant enrollment.
 - c. Recruitment of Participants Including information on the participant recruitment process.
 - d. A copy of the consent form. If applicable, a copy of the assent form.

e.

If the Principal Investigator or Co-Investigator is faculty of a university or is associated with an institution, a copy of the university's or institution's research review entity's decision (most generally from an Institutional Review Board (IRB) needs to be submitted. If the Principal Investigator or Co-Investigator lack an institutional research review entity's decision, then they may submit a waiver request.

- f. Dissemination:
 - i. A copy of the proposed procedures to maintain confidentiality and anonymity.
- g. Funding Information
- h. Signed principal investigator assurance
- 4. If the proposal includes a survey or questionnaire, interview guide(s) and/or other data collection material, copies will need to be submitted for approval before distribution to participants.
- 5. Curriculum vitae (CV) or résumés of all project staff.
- 6. Budget.

- 7. Timeline.
- 8. Proof of human subjects' protection training completion for key research personnel including those working directly with the community.
- 9. Procedure for reporting adverse events (ex. Participant's discomfort, breach of data confidentiality, etc.)
- B. Renewal/Modification Application. Renewal applications are required at one-year intervals from the date of initial review or more frequently as may be required by the RRC. The RRC 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 RRC approval before the renewal application is due, a modification application must be completed documenting the changes. 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. A renewal/modification application is considered complete when the investigators provide 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 RRC review and Council approval prior to implementation. A complete *Abstract, Publications, Presentation*

(APP) form must be completed for RRC review. An APP form is considered complete when the investigator(s) provides the following:

- 1. Review request.
- 2. Disclosure of previous RRC approval.
- 3. A copy of the Seneca Nation 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 Withdrawal of Research.

- 1. Project Closure. Research approved by Council 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 RRC may close approved projects. Procedures for closing a study fall into five categories:

- i. Closure due to receipt and approval of the project closure form
- ii. Closure after expired approval RRC 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 RRC (6 months from last board decision letter)
- v. Withdraw request initiated by PI
- 2. For a lapsed protocol, PI must submit a project closure form and a renewal form.
- 3. To close or withdraw a project, the PI must submit a project 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.
- 5. If re-opening a previously closed protocol for publication purposes only, same protocol number will be used. A renewal form and the APP form must be submitted to the RRC.

SECTION VI. RECORDS

A. The RRC shall maintain the following records for a minimum of five (5) years after the conclusion of the last RRC 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 RRC meetings, minutes of continuing review activities, and copies of

all correspondence between the RRC and the research investigators.

SECTION VII. REPORTING PROCEDURES

The RRC shall promptly report information to the Council. Investigators are required to use the RRC reporting form. The RRC shall follow the procedures outlined below:

- A. Regarding Individual Research Protocols (Compliance Problems, Deviations, Violations and Events Encountered During the Provision of Research)
 - 1. **Problems:** The RRC 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 SNHB RRC within 15 working days of the event. The RRC will track the number of Problems associated with a protocol to determine if the protocol or consent document should be changed.
 - 2. **Protocol and Regulatory Deviations:** Protocol and Regulatory Deviations or Violations are any actions or events that are not in accordance with the approved protocol, RRC policies, federal regulations or RRC 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;
 - 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 RRC within 15 working days of noting the deviation.
 - d. The RRC 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.

- 3. **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 or the Nation.
 - 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 Nation-specific data or analysis in research that were to remain unidentified and that contained potentially stigmatizing or other harmful information;
 - Failure to obtain Nation approval for protocol modifications as required by the RRC; or
 - b. Investigators must report protocol violations within five (5) working days of noting the violation.

B. The RRC will handle Protocol and Regulatory Violations as Unexpected Serious Adverse Events, below:

1. Serious Adverse Events (SAE)

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 SNHB RRC considers harm to include physical, psychological, social, cultural, economic, legal, dignitary or privacy. The RRC 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, cultural, economic, legal, or dignitary status or infringing on their privacy.

2. Expected Serious Adverse Events (ESAE)

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.

- a. The SNHB RRC requires Investigators to report expected serious adverse events as they occur, in order for the RRC to track the severity and number of expected serious adverse events.
- b. At the time of initial 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 (USAE)

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 Nation;
 - Unexpected human subject suicidal ideation;
 - Unexpected enrollment of a vulnerable subject 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 RRC and all other review entities that have oversight of the research within 24 hours.
- iii. Failure to contact the RRC within the required time may result in further actions by the RRC.
- iv. The RRC Chair will immediately issue written notification to the Council and the SNHS CEO.
- v. Depending on the nature of the Event, the RRC 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) Project Officer and/or grants manager of the funding agency
 - 4) Other federal agencies as required, and
 - 5) All other review entities that have oversight of or responsibility for the research.
- vi. For all other Unexpected Serious Adverse Events, Investigators must contact the RRC Chair and all other review entities that have oversight of the research within five (5) working days of learning of the Event.
- vii. After being informed of an Unexpected Serious Adverse Event, the RRC will reexamine 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 Council Approval of Research

- 1. Council 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 RRC decisions, conditions and/or requirements; or

- b. The research has been associated with unexpected serious harm to participants.
- c. The decision to permanently suspend or terminate research activities is recommended by the full RRC.

D. Immediate Suspension

- 1. The RRC 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 the Nation. The serious potential harm may be physical, psychological, social, cultural, 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.
- 2. The SNHB RRC will notify the researcher, the researcher's primary review entity, and Council.
- 3. As soon as is practicable after the immediate temporary suspension, the RRC Chair, if advised by Council, will meet with the researcher, research staff, complainants (if any), and other appropriate people, to discover the full facts of the situation. Council will determine the course of future action, which may include remedial components. Full due process will continue to be maintained. The full RRC and Council must review and approve the proposed final resolution. If requested by Council, the RRC Chair will notify the researcher, the researcher's home review entity in writing about the final resolution.

E. Termination

Council may move to terminate research if:

- 1) Unresolved protocol and regulatory violations cause significant harm to research participants.
- 2) Unresolved unexpected serious adverse events are ongoing are unresolved.
- 3) Continuing non-compliance to Council direction, if after suspension has occurred.
- 4) Reported adverse events are so egregious they affect the rights and welfare of human research participants.

F. Procedures to Report Termination or Suspension.

If protocol approval is suspended or terminated, the RRC will report within five [5] working days to the following officials and institutions:

- i. Investigator's host institution's Institutional official
- ii. Investigator's host institution's Office of Sponsored Programs
- iii. Project Officer and/or grants manager of the funding agency
- iv. Other federal agencies as required, and
- v. All other review entities that have oversight of or responsibility for the research.

G. Regarding RRC Proceedings and Procedures.

RRC correspondence containing a summary of results of RRC deliberations shall be reported at the next scheduled SNHB meeting and submitted to Council as an attachment to the SNHB minutes.

SECTION VIII. STUDENT RRC GUIDANCE

The SNHB RRC is committed to assisting Seneca Nation students in learning, understanding, and navigating the RRC process. Members of the SNHB RRC will mentor and advise students in need of this guidance.

SECTION IX. FEE SCHEDULE

The SNHB RRC will charge for-profit and non-profit entities, and State, Federal, and academic institutions for review of their protocols, at the discretion of the RRC. Fee waivers will be decided on a case-by-case basis. Seneca Nation students will be exempt from the fee schedule. The fee schedule will be as follows:

- A. \$1,200 for full committee review (initial one-time fee).
- B. \$500 for RRC comment and review (per protocol).
- C. \$250 for continuing or expedited review (yearly fee).
- D. \$50 for Processing/Administration Fee (per review).
- E. \$50 for consultation (per protocol).

SECTION X. POINT OF CONTACT

Mailing address: [RESERVED]

Email address: [RESERVED]

SECTION XI. CREDITS

Southwest Tribal Institutional Review Board – approved sharing of their template for construction of the SNHB RRC Policy and Procedures document.

Indigenous Wellness and Research Institute, University of Washington: Sample Research Protocol Code, Section 1, General Policy Background Statement; Section 8, Regulations of Biological Samples. http://iwri.org/resource area/research-templates/

National Congress of American Indians – Research Review Checklist for American Indian and Alaska Native Communities. (Research Regulation Toolkit; Sahota, PC)

Research Ethics Training for Health in Indigenous Communities (rETHICS), 2018; Pearson, C, Parker, M, Fisher, C. University of Washington. (Permission to use, 10/03/2019, C.

Pearson email communication to T. Parker.)

SECTION XII. RELEVANT REPORT & REGULATIONS

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html (Viewed 04/12/2020).

Seneca Nation Regulation of Biological Samples (Adopted by the Seneca Nation Council June 12, 2021)

Title 45 C.F.R., Part 46, Protection of Human Subjects; Pre 2018. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Title 45 C.F.R., Part 46, Protection of Human Subjects; 2018. Subpart A. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Title 21 C.F.R., Part 50, Protection of Human Subjects. Rev. April 1, 2019. (Applies to all clinical investigations regulated by the Food and Drug Administration, e.g., drugs for human use, medical devices for human use, biological products for human use). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=50

APPENDIX A – [RESERVED]

SENECA NATION RESEARCH POLICY

Recognizing the need to provide adequate protection to its members from unwarranted personal intrusion, the Seneca Nation ("Nation") wishes to establish this policy to control all research done on the Nation territories involving either personal contact with individuals to gather information, research through the use of Nation official records, or through any other data derived from records, including computerized information, of any Nation department.

The first step in initiating a research program or request of official data, on the territories should be the submission of a written proposal to the Office of the Seneca Nation President. The exception is requests for health or medical research. Such research request will follow the established guidelines posted on the Seneca Nation Health System website. For other types of research, in general, the proposal should state the purpose of the work, methods of gathering data, vitae of researchers, expected outcomes and should also include a timetable. Expressly stated in the proposal should be a statement of how the proposed research will benefit the people of the Seneca Nation. Include a resume of the principal investigator(s) for the project and copies of proposals submitted to funding agencies. The proposal will be submitted to the Council and the researcher(s) may be asked to appear either to talk with the Councillors and the Executives or to answer questions directly in Council. Permission for the project will be granted or denied by the Council and the researcher(s) should assume that a time limit will be set on the proposed project. Should the project overrun the allotted time, extensions may be granted by Council on the basis of a written request for extension.

If it is expected that the resulting publication, film, etc. will result in a profit, arrangements for sharing a percentage of that profit with the Nation will be made before the research is approved.

Should the proposed work call for personal interviews, individual permission must be obtained from each person to be interviewed. Project permission granted by Council will not obligate any or all Seneca people to cooperate in the research, but rather will allow the researcher to approach the people to seek individual permission.

APPENDIX B

If questionnaires are to be used, the researcher should check with the Nation Clerk's office to assure compliance with local regulations regarding either door-to-door solicitation or mail regulations.

If Nation records are to be used in the research, arrangements will need to be made with the appropriate departments to secure access to the records at times and in circumstances acceptable to that department.

It must be stressed that, at all times, the greatest care must be taken to assure confidentiality of the individual, whether the approach is personal or through the use of records such as health records, financial records, enrollment records, etc. If there is any chance of breach of confidentiality of the individual, approach must be made either to the individual of the heirs of the individual to seek permission to use information gathered by that individual. In such a case, it must be reported to the individual from whom permission is sought that the use of the information in the resulting report will cause a likely breach of confidentiality. The individual is free to either give or deny permission to use such data. It is recognized by the Nation that the use of computers and the internet has given the unique ability to gather a great deal of information about individuals, some of which may be either compromising or embarrassing to that individual. These data are never to be used without express permission of the individual, either in publication or report. Information potentially damaging to the individual should be destroyed in the researcher's records in order to avoid compromising the individual.

If it is customary to pay informants off the territories, it shall be customary on territory as well, with informants being paid at the current rate. If it is customary to award gifts or tokens to respondents in a survey off territory, the same shall hold true on territory. These arrangements for informant rate of pay, etc., should be included in the proposal. In general, Respondents either to personal interviews or questionnaires shall be treated in the same manner as similar people off the territory.

If it shall be necessary to hire local people to aid in the research, preference shall be given to Seneca or other Hodinöhsö:ni' people in the community. Lists of qualified and available people can be obtained from the Nation HR Office or appropriate department.

APPENDIX B

Copies of all documents, reports, tapes, photographs, etc., developed as a result of the

project will be placed with the Nation where they will be available for all interested people.

It must be stressed once more that all research involving either personal contact or the use

of written or computerized records must be cleared in advance by the Council. No residence for

the end purpose of research may be taken up on the reservation of the Nation prior to approval of

the research. No work may be done prior to receiving permission. This includes such studies as

sociological studies, anthropological studies, genealogical studies, demographic studies,

environmental studies, etc. Permission will be granted or denied based on the value of the

proposed study to the Seneca people.

Adopted by the Seneca Nation Council August 18, 1986.

Amended by the Seneca Nation Council June 12, 2021.

Office of the President Seneca Nation

12837 Route 438

Irving, NY 14081

(716) 532-4900

SENECA NATION REGULATION OF BIOLOGICAL SAMPLES

Any researcher who seeks to collect, acquire, store (or bank), or analyze any biological samples must agree and abide by the following conditions with regard to research with biological materials.

The Seneca Nation may, at any time, decide to withdraw from the research project or any portion thereof, and request the return of all biological samples. The researcher, and any other parties, must comply.

Upon completion of the research project, or termination or cancellation of the project at any time prior to completion, the biological samples must be completely and fully returned to the possession of the Seneca Nation, or disposed of as directed by the Seneca Nation.

No biological samples from this study may be released to, or used by, any other researcher(s), research institution, or any other entity, whether public or private, without the prior and fully-informed written approval of the Seneca Nation.

If the Seneca Nation permits any biological samples to be stored in any other locations, the researcher shall maintain at all times a complete list thereof. The list shall include a description of the sample or data, source, specific use or purpose of each item, responsible person(s) at the location, and where the item is housed (e.g., in a "gene bank" or on a specific computer), and any relevant time lines with regard to use of, disposition, return, or destruction of the samples or data.

The researcher shall provide an updated copy of the list to the Seneca Nation whenever changes are made. The updated list shall include identification of changes made since the last copy of the list was provided to the Seneca Nation.

Any situation where biological samples will leave the possession or control of the researcher will require a separate agreement between the Seneca Nation and the external party in accordance with this Regulation.

The Seneca Nation prohibits identification of any enrolled member participating in a Seneca Nation approved investigation through any manipulation of genomic data or genome tracing.

No entity may seek to patent or commercialize any biological materials obtained from the Seneca Nation, from the Seneca Nation's jurisdiction, or under the authority of the Seneca Nation. This includes genetic samples, any copies of the original genetic samples, any cell lines containing copies of the original genetic samples, and data derived from these samples.

Approved by the Seneca Nation Council June 12, 2021.