



# SAINT REGIS MOHAWK TRIBE

## Research Policy

### 1. PURPOSE

This policy establishes guidelines for responsibly conducting scientific research within the Saint Regis Mohawk Tribe (“SRMT”) Territory or involving Tribal members. This policy also provides the steps to be taken in response to instances of alleged research misconduct.

### 2. POLICY STATEMENT

- 2.01 The Saint Regis Mohawk Tribe is a federally recognized tribe. The Saint Regis Mohawk Tribal Council (“Tribal Council”) is responsible for the health and safety of community members. The Tribal Council has determined that before conducting any activity that includes research involving human subjects on the Saint Regis Mohawk Reservation or data that the Saint Regis Mohawk Tribe has in its possession, a researcher must first seek the approval of the Tribal Council or its designee.

The research must be approved by an Institutional Review Board (IRB), and the researcher must be specifically assigned to the research project.

The research must adhere to the following core principles:

- **Respect for the Saint Regis Mohawk Tribe’s Sovereignty:** All research activities must recognize and respect the sovereignty of the tribal government and its authority over tribal lands, resources, and data.
- **Cultural Sensitivity:** Researchers must demonstrate an understanding of and respect for tribal cultural values, traditions, and practices.
- **Data Protection:** Sensitive information, including personal, cultural, and proprietary data, must be protected from unauthorized access and misuse.

### 3. SCOPE

- 3.01 This policy applies to all research conducted within the SRMT territory and with SRMT Tribal members. This policy also applies to requests for release of data for research purposes, including data held by Tribal divisions, programs, and affiliated entities.

This statement of policy and procedures is intended to carry out the Tribe’s responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. •

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• Sections based on 42 CFR Part 93 have endnotes indicating the applicable section.

This document applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving:

- A person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with the Tribe;<sup>i</sup> and
- (1) PHS support biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information, (2) applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training, or (3) plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.<sup>ii</sup>

This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date the Tribe or Health and Human Services (HHS) received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

## 4. RESPONSIBILITY

### 4.01 Researchers

- **Proposal Submission:** Submit a detailed research proposal outlining the objectives, methodology, and data requirements.
- **Ethical Compliance:** Ensure that the research adheres to ethical standards and respects the rights and welfare of participants.
- **Informed Consent:** Obtain informed consent from participants, explaining the nature and purpose of the research.
- **Data Security:** Implement measures to protect sensitive data from unauthorized access and misuse.
- **Reporting:** Provide regular updates on the research progress and submit a final report upon completion.
- **Confidentiality:** Maintain the confidentiality of all sensitive information and use it solely for approved research purposes.

**Saint Regis Mohawk Tribal Council or designee:**

- **Review and Approval:** Establish a review committee to evaluate research proposals based on their potential benefits, ethical standards, and data protection measures.
- **Data Sharing Agreement:** Enter into agreements with researchers outlining the terms and conditions of data access, including confidentiality and security requirements.
- **Monitoring:** Monitor research activities to ensure compliance with the approved proposal and data-sharing agreement.

**Tribal Research Review Committee (TRRC):**

- **Evaluation:** Assess research proposals for their alignment with tribal priorities, ethical standards, and potential benefits.
- **Cultural Sensitivity:** Ensure that research activities respect tribal cultural values and practices.
- **Feedback:** Provide feedback to researchers on their proposals and suggest necessary modifications.

These responsibilities help ensure that research conducted within the tribal community is ethical, respectful, and beneficial to the tribe.

**5. DEFINITIONS**

5.1 Ethical Standards means the Researcher shall adhere to the following:

1) Respect for Tribal Sovereignty & Law

Recognize and uphold the Tribe's sovereign authority over all research within its jurisdiction.

Comply with Tribal Council resolutions, division/program policies, and all conditions set by the Tribal Research Review Committee ("TRRC").

Secure written authorization before any engagement, and obtain additional approvals for any scope change, method change, or new data use.

2) Community Benefit & Co-Design

Design research to deliver tangible benefits to the community (capacity building, program improvement, data dashboards, training, etc.).

Involve tribal divisions/programs and community representatives in planning, instrument

design, and interpretation.

Share interim findings with relevant tribal programs to support continuous improvement, not just final publication.

### 3) Cultural Safety & Protocols

Follow designated cultural protocols (e.g., who can request, record, interpret, or store cultural knowledge).

Obtain explicit, written permissions for ceremonies, language recordings, or culturally sensitive content; in some cases, no recording may be permitted.

Use culturally appropriate methods, locations, timelines, and languages; compensate cultural consultants and interpreters fairly.

### 4) Informed Consent & Participant Protections

Provide clear, plain-language consent forms describing purpose, procedures, risks, benefits, data handling, withdrawal rights, and contacts.

Obtain voluntary, documented consent (and assent for minors, with guardian consent).

Protect vulnerable populations (children, elders, individuals with disabilities) with heightened safeguards.

Ensure participation does not affect any eligibility for tribal services.

### 5) Privacy, Confidentiality & Data Security

Minimize collection to only what is necessary; de-identify where possible.

Store data in encrypted systems; restrict access to authorized personnel named in the MOU/IRB approval.

Never share raw data beyond approved parties; do not upload to external platforms or AI tools without written tribal approval.

Establish and follow a Data Management Plan approved by TRRC, including retention periods and destruction timelines.

### 6) Data Governance & Ownership

Recognize that all data collected under this policy is the property of the Tribe.

Use, share, or publish data only as permitted in the signed Data Sharing Agreement.

Return clean, well-documented data files to the Tribe; ensure portability and future usability.

#### 7) Intellectual Property (“IP”) & Traditional Knowledge

The Tribe retains IP over culturally derived knowledge, recordings, and materials. No commercialization, patenting, or licensing from tribal knowledge or biospecimens without explicit, prior tribal authorization outlining community benefit and revenue sharing.

Respect restrictions on genetic, archeological, linguistic, or ceremonial materials.

#### 8) Transparency, Integrity & Conflicts of Interest

Disclose all funding sources, affiliations, and potential conflicts to the TRRC and participants.

Register studies when applicable; pre-specify analysis plans to reduce bias.

Prohibit fabrication, falsification, plagiarism, and undisclosed secondary use of data. Promptly report protocol deviations, adverse events, or breaches to the TRRC.

#### 9) Safety, Risk Management & Environmental Care

Conduct a risk assessment covering physical, psychological, cultural, and environmental risks.

Maintain appropriate insurance, emergency procedures, and incident reporting pathways.

Avoid environmental harm; obtain permits for any fieldwork, sampling, or drone use; follow Tribal environmental regulations.

#### 10) Fair Compensation & Logistics

Provide equitable compensation for participants, cultural advisors, and interpreters; ensure compensation does not coerce participation.

Offer transportation, accessible venues, and language support as needed.

#### 11) Training & Qualifications

Ensure all team members complete training in: research ethics, privacy/security, and safety.

Use qualified interpreters; avoid relying on minors or untrained family members for

translation.

## 12) Monitoring, Reporting & Dissemination

Submit interim updates per schedule; provide a final report to TRRC before any public dissemination.

Co-develop dissemination plans with tribal divisions/programs; prioritize community-friendly formats (plain language briefs, visuals, community meetings).

Secure written publication approval; include tribal acknowledgments as specified; remove any details TRRC identifies as sensitive.

## 13) Grievances & Accountability

Provide a clear channel for participant complaints and concerns; respond respectfully and promptly.

Cooperate with audits, monitoring visits, and corrective actions required by TRRC.

Understand that violations may result in suspension, revocation, legal action under Tribal law, and notifications to funders/IRBs.

## 14) Offboarding & Legacy Stewardship

At project close, return all materials, metadata, and documentation; certify secure destruction of non-retained copies.

Support knowledge transfer: trainings, tool hand-offs, and capacity-building so the Tribe can use results independently.

- 5.2 **Deciding Official (DO)** means the Tribal official who makes final determinations on allegations of research misconduct and any Tribal administrative actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the Tribe's inquiry, investigation, or allegation assessment. A DO's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement. This position is the responsibility of the SRMT Executive Director, or his/her designee.
- 5.3 **Office of Research Integrity or ORI** means the office established by Public Health Service Act section 493 (42 U.S.C. 289b) and to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS-supported activities.
- 5.4 **Research Integrity Officer (RIO)** means the Tribal official responsible for: (1)

assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. This position will be the responsibility of the SRMT Executive Director, or his/her designee.

- 5.5 **Research misconduct involving Public Health Service (PHS) support** is contrary to the interests of the PHS and the Federal Government, to the health and safety of the public, to the integrity of research, and to the conservation of public funds.

(b) The U.S. Department of Health and Human Services (HHS) and institutions that apply for or receive PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training share responsibility for the integrity of the research process. HHS has ultimate oversight authority for PHS-supported research, and for taking other actions as appropriate or necessary, including the right to assess allegations and to perform inquiries or investigations at any time. Institutions and institutional members have an affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS-supported work, and primary responsibility for responding to and reporting allegations of research misconduct, as provided in this part.

## 6. PROCEDURES

- 6.1 If there has been no IRB approval, the researcher must submit a research application to the Tribal Council or its designee. The application shall contain the following information:

1. Indicate New or Renewal Application
2. Study protocol
  - a. Background and Scientific rationale (1 paragraph)
  - b. Anticipated End Date
  - c. Participant Inclusion/Exclusion Criteria
  - d. Participant Enrollment
  - e. Recruitment and Screening Procedures
  - f. Informed Consent Process
  - g. Data Collection Procedures
  - h. For Community-Engaged Projects, address:
    - i. identification of the community partners, how the partnership was formed and how will the community be involved throughout the project (roles and responsibilities);
    - ii. any literacy issues, language barriers, cultural sensitivities, etc; and
    - iii. how research processes and outcomes will benefit the community and how they will be disseminated to the community.
  - g. Use of Medical Device or Drugs
  - h. Use or Collection of Protected Health Information
  - i. Use or Collection of Educational Records

- j. Project Location(s)
- k. Participant Compensation
- l. Project Resources
- m. Potential Risks of Harm
- n. Potential Benefits
- o. Privacy of Participants
- p. Unanticipated Problems/Adverse Events
- q. Participant Complaints
- r. Data Management Procedures and Confidentiality
- s. Data Analysis/Statistical Considerations
- t. Participant Withdrawal
- 3. CV of Principal Investigator, Co-Investigators, and Key Personnel
- 4. Data Collection Instruments
- 5. Consent Form
- 6. Assent Form
- 7. Recruitment Materials
- 8. Other Supporting Documents

- 6.2 If the research was previously approved by an Institutional Review Board (“IRB”), the researcher shall submit proof of such approval, and the Tribal Council or its designee may give its permission to move forward with a data-sharing agreement in place.

The Tribal Council or its designee might seek further information from the researcher to include the original application submitted to the IRB.

The Tribal Council will render based on the following:

- **Approval Criteria:** Applications will be evaluated based on their potential benefits to the tribe, adherence to ethical standards, and measures for data protection. Priority will be given to research that aligns with tribal priorities and interests.
- **Data Sharing Agreement:** Approved researchers must enter into a data sharing agreement with the tribal government, outlining the terms and conditions of data access, including confidentiality, data security, and reporting requirements.
- **Monitoring and Reporting:** Researchers must provide regular updates to the tribal government on their research progress and submit a final report upon completion. The tribal government reserves the right to monitor research activities to ensure compliance with the agreement.

- 6.3 If the application is approved, the following confidentiality and data security are required:

- **Confidentiality:** Researchers must maintain the confidentiality of all sensitive information and use it solely for the purposes outlined in the approved research proposal.
  - **Data Security:** Researchers must implement appropriate data security measures to protect tribal information from unauthorized access, loss, or misuse.
  - **Intellectual Property:** The tribal government retains ownership of all data and information shared with researchers. Any publications or presentations resulting from the research must acknowledge the contribution of the tribal government and comply with any additional requirements specified in the data-sharing agreement.
- 6.4 Once the research is complete, the research report will be reviewed by the TRRC to ensure the research was conducted in accordance with the research agreement.
- 6.5 The TRRC and the Researcher shall submit a copy to Tribal Council for review.
- 6.6 If a Tribal Council Resolution is required to validate the research, the researcher shall present to Tribal Council, Executive Director, and any responsible tribal representative prior to approval.
- 7. CONSEQUENCES FOR VIOLATING THIS POLICY:**
- 7.1 If there is a violation of this policy, the research access and all information gathered in the process will be void, and the research must return all data.

#### Research Integrity Officer

The SRMT Executive Director, or his/her designee will serve as the RIO who will have primary responsibility for implementing the Tribe's policies and procedures on research misconduct. These responsibilities include the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct in accordance with Section V.A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify ORI of special circumstances, in accordance with Section IV.F. of this policy;
- Sequester research data and evidence pertinent to the allegation of research

- misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and Tribal policy;
  - Notify the respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports in accordance with Section III.C. of this policy;
  - Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
  - Appoint the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
  - Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
  - In cooperation with other Tribal officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counteract potential or actual retaliation against them by respondents or other Tribal members;
  - Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;
  - Notify and make reports to ORI as required by 42 CFR Part 93;
  - Ensure that administrative actions taken by the Tribe and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
  - Maintain records of the research misconduct proceeding and make them available to ORI in accordance with Section VIII.F. of this policy.

## 7.2 Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction.

### 7.3 Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;<sup>iii</sup>
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;<sup>iv</sup>
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 and the Tribe's policies and procedures on research misconduct;<sup>v</sup>
- Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the Tribe decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;<sup>vi</sup>
- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;<sup>vii</sup>
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation;<sup>viii</sup> and
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the Tribe and addressed in the final report.<sup>ix</sup>

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other Tribal officials, the Deciding Official may terminate the Tribe's review of an allegation that has been admitted, if the Tribe's acceptance of the admission and any proposed settlement is approved by Office of Research Integrity (ORI) as per 42 CFR § 93.316.<sup>x</sup>

### 7.4 Deciding Official

The DO will receive the inquiry report and after consulting with the RIO and/or other Tribal officials, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI may assess the reasons why the Tribe decided not to investigate.<sup>xi</sup>

The DO will receive the investigation report and, after consulting with the RIO and/or other Tribal officials, decide the extent to which the Tribe accepts the findings of the investigation and, if research misconduct is found, decide what, if any, administrative actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to ORI, as required by 42 CFR § 93.315.

## **8. General Policies and Principles**

### **8.1 Responsibility to Report Misconduct**

All research personnel, including scientists, research assistants, and others involved in the study's conduct and reporting, will report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO at [518-358-2272](tel:518-358-2272) to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

### **8.2 Cooperation with Research Misconduct Proceedings**

Tribal employees will cooperate with the RIO and other Tribal officials in the review of allegations and the conduct of inquiries and investigations. Tribal employees, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other Tribal officials.

### **8.3 Confidentiality**

The RIO shall, as required by 42 CFR § 93.108: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The RIO should use written confidentiality

agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

#### 8.4 Protecting complainants, witnesses, and committee members

Tribal employees and elected officials or agents and contractors of the Tribe may not retaliate in any way against complainants, witnesses, or research participants. Tribal employees and elected officials or contractors and agents of the Tribe should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

#### 8.5 Protecting the Respondent

As requested, and as appropriate, the RIO and other Tribal employees and elected officials or Tribal agents or contractors shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.<sup>xiii</sup>

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the Tribe. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case.

#### 8.6 Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the Public Health Service (PHS) supported research process. In the event of such a threat, the RIO will, in consultation with other Tribal employees and ORI, take appropriate interim action to protect against any such threat.<sup>xiii</sup> Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human subjects;
- HHS resources or interests are threatened;
- Research activities should be suspended;

- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.<sup>xiv</sup>

## 9. Conducting the Assessment and Inquiry

### A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103.<sup>xv</sup> An inquiry must be conducted if these criteria are met.

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph C. of this section.

### B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.<sup>xvi</sup>

### C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in

writing. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.<sup>xvii</sup> The RIO may consult with ORI for advice and assistance in this regard.

## 10. The Inquiry Report

### A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the Public Health Service (PHS) support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant.<sup>xviii</sup>

The Tribe's General Counsel or its designee should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

### B. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within **15 days** and include a copy of or refer to 42 CFR Part 93 and the Tribe's policies and procedures on research misconduct.<sup>xix</sup> The RIO may notify the complainant whether the inquiry found an investigation to be warranted and provide relevant portions of the inquiry report to the complainant for comment within 15 days. A confidentiality agreement will be a condition for access to the report.

Any comments that are submitted by the respondent or complainant will be attached to the final inquiry report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the RIO.

### C. Tribal Decision and Notification

#### 1. Decision by Deciding Official

The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted.

2. Notification to ORI

Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI with the DO's written decision and a copy of the inquiry report. The RIO will also notify those Tribal employees and elected officials who need to know of the DO's decision. The RIO must provide the following information to ORI upon request: (1) the Tribe's policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.<sup>xx</sup>

3. Documentation of Decision Not to Investigate

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

## 11. Conducting the Investigation

### A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted.<sup>xxi</sup> The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. Under 42 CFR § 93.313 the findings of the investigation must be set forth in an investigation report.

### B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) notify the respondent in writing of the

allegations to be investigated. The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.<sup>xxii</sup>

The RIO will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the Tribe's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.<sup>xxiii</sup>

C. ORI Jurisdiction

ORI does not have jurisdiction to review a research misconduct investigation or compliance or a retaliation issue related to non-PHS funded research. ORI jurisdiction only extends to projects for which PHS funds are requested or provided; the existence of an assurance does not give ORI authority over non-PHS matters (42 U.S.C. Part 289b (b), 42 C.F.R. Part 93.102.)

## 12. The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the respondent;
- Describes and documents the PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the Tribe's policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and

- Includes a statement of findings for each allegation of research misconduct identified during the investigation.<sup>xxiv</sup> Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific PHS support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.<sup>xxv</sup>

#### C. Comments on the Draft Report and Access to Evidence

##### 1. Respondent

The RIO must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.<sup>xxvi</sup>

##### 2. Confidentiality

In distributing the draft report, or portions thereof, to the respondent, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

#### D. Decision by Deciding Official

The RIO will assist in finalizing the draft investigation report, including ensuring that the respondent's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the Tribe accepts the investigation report, its findings, and the recommended actions; and (2) the appropriate actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the RIO, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision. When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing. After

informing ORI, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

E. Notice to ORI of the Tribe’s Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation submit the following to ORI: (1) a copy of the final investigation report with all attachments (2) a statement of whether the Tribe accepts the findings of the investigation report (3) a statement of whether the Tribe found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.<sup>xxvii</sup>

F. Maintaining Records for Review by ORI

The RIO must maintain and provide to ORI upon request “records of research misconduct proceedings” as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation.<sup>xxviii</sup> The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of the Tribe’s handling of such an allegation.<sup>xxix</sup>

**13. Completion of Cases; Reporting Premature Closures to ORI**

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.<sup>xxx</sup>

**14. Administrative Actions by the Tribe**

If the DO determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person from the particular project,
- Report any findings of research misconduct to the appropriate funding agency or research oversight authority;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the research misconduct.

**15. ATTACHMENTS**

15.01 Research Request Application

**16. REFERENCES, RELATED DOCUMENTS**

16.01 This section refers the reader to other documents or information upon which this Policy is based or which may contain data that needs to be reviewed when dealing with the subject matter.

**17. AMENDMENT**

17.01 This policy may be amended from time to time by the Tribe.

**18. EFFECTIVE DATE**

18.01 This policy shall take effect on the date signed by Tribal Council.

**SAINT REGIS MOHAWK TRIBAL COUNCIL**



Michael Connors  
Tribal Chief



Donald Thompson, Jr.  
Tribal Chief



Ross Garrow  
Tribal Chief

Date: March 30, 2026

<sup>i</sup> 42 CFR § 93.214

<sup>ii</sup> 42 CFR § 93.102

<sup>iii</sup> 42 CFR §§ 93.304(c), 93.307(b)

<sup>iv</sup> 42 CFR §§ 93.304(e), 93.307(f)

<sup>v</sup> 42 CFR § 308(a)

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- vi 42 CFR § 310(c)
  - vii 42 CFR § 310(g)
  - viii 42 CFR § 310(g)
  - ix 42 CFR §§ 93.304(f), 93.312(a)
  - x 42 CFR § 93.316
  - xi 42 CFR § 93.309(c)
  - xii 42 CFR § 93.304(k)
  - xiii 42 CFR § 93.304(h)
  - xiv 42 CFR § 93.318
  - xv 42 CFR § 93.307(a)
  - xvi 42 CFR § 93.307(c)
  - xvii 42 CFR §§ 93.305, 93.307(b)
  - xviii 42 CFR § 93.309(a)
  - xix 42 CFR § 93.308(a)
  - xx 42 CFR § 93.309(a) and (b)
  - xxi 42 CFR § 93.310(a)
  - xxii 42 CFR § 93.310(b) and (c)
  - xxiii 42 CFR § 93.310(d)
  - xxiv 42 CFR § 93.313
  - xxv 42 CFR § 93.313(f)
  - xxvi 42 CFR §§ 93.312(a), 93.313(g)
  - xxvii 42 CFR § 93.315
  - xxviii 42 CFR § 93.317(b)
  - xxix 42 CFR §§ 93.300(g), 93.403(b) and (d)
  - xxx 42 CFR § 93.316(a)