Sitka Tribe of Alaska
Administration Policy and Procedures
Responding to Allegations
of Research Misconduct under Federal Research Awards

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I. Introduction

A. General Policy and Authority

The United States Department of Health and Human Services (DHHS) has determined, pursuant to 42 CFR Part 93, that organizations receiving federal awards for research are required to have a policy and procedure compliant with 42 CFR Part 93. These regulations require STA to inform its staff, contractors, and sub-recipients conducting research of its Small Organization Statement regarding Research Misconduct, to keep a copy of the statement on file, to take necessary immediate or interim administrative actions to handle allegations, to protect the confidentiality of the whistleblower and the respondent, and to cooperate with and report to the DHHS's Office of Research Integrity, or other applicable federal agency office in charge of research misconduct.

As a federally recognized tribal government, the Sitka Tribe of Alaska (STA) has adopted a Research Policy pursuant to its Tribal Constitution. This policy contains STA's policy regarding research on citizens, ancestors, language, culture, traditional knowledge, lands, waters, and natural resources of the Tribe. As a condition of receiving federal funding for research from the United States government, STA adopts this special policy and procedure applicable to the conduct and behavior of researchers.

Sitka Tribe of Alaska (STA) is a small organization compared to other research institutions. As such, it does not have the administrative capacity to conduct an inquiry or investigation into an allegation of research misconduct without real or apparent conflicts of interest as required by applicable federal regulations, such as 42 CFR Part 93. Pursuant to 42 CFR 93.302, STA adopts this special policy and procedure.

STA intends this policy and procedure to apply to all federally supported research such, agency-specific terms such as PHS, ORI, and 42 CFR Part 93 shall always be interpreted to mean PHS or other applicable federal agency, ORI or other applicable federal office responsible for research misconduct, and 42 CFR Part 93 or other applicable federal regulation.

B. Scope

This statement of policy and procedures is intended to carry out the Sitka Tribe of Alaska's

responsibilities under applicable federal regulations, including 42 CFR Part 93, when conducting federally sponsored research.

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 STA;[1] and

- (1) PHS supported 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.[2]

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

II. Definitions

The terms used in this special policy and procedure have the same meaning as given in the Public Health Service Policies on Research Misconduct, 42 CFR Part 93.

Designated Misconduct Policy and Procedures Official (Designated Official or DO) means the STA official responsible for (1) receiving allegations of research misconduct and reporting them to the

applicable federal agency office in charge of research misconduct, (2) communicating and cooperating with any investigation into research misconduct; and (3) the other responsibilities described in this policy.

Researcher or Researchers means an STA employee conducting research under a federal award on behalf of STA or an employee of another organization that has received funding from or through STA to conduct research under a federal award.

III. Rights and Responsibilities

A. Designated Misconduct Policy and Procedures Official

The STA Chief Executive Officer will appoint the Designated Official, who will be primarily responsible for implementing policies and procedures regarding research misconduct. A detailed listing of the responsibilities of the DO is outlined in Appendix A. 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;
- Upon becoming aware of an allegation or other evidence of possible research misconduct, the DO of Sitka Tribe of Alaska will immediately contact the Office of Research Integrity (ORI) at (240) 453-8400
- As necessary, take interim action and notify the ORI of special circumstances in accordance with Section IV 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 STA policy;
- In cooperation with other STA officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other researchers;
- Notify and make reports to ORI as required by 42 CFR Part 93;
- Ensure that administrative actions taken by STA 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.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation.

C. 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 to notify the respondent in writing at the time of or before beginning an inquiry;[3]
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;[4]
- 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 STA's policies and procedures on research misconduct;[5]
- 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 STA decides to start 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;[6]
- 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;[7]
- 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;[8] 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. Be notified that any comments must be submitted within 30 days of the date on which a copy was received. The comments will be considered by STA and addressed in the final report.[9]
- The respondent should be given the opportunity to admit that research misconduct occurred and that they committed the research misconduct.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

Researchers will report observed, suspected, or apparent research misconduct to the DO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, they may meet with or contact the DO 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 DO will refer the individual or allegation to other offices or officials responsible for resolving the problem.

At any time, a researcher may have confidential discussions and consultations with the DO about concerns of possible misconduct and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

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

C. Confidentiality

The DO shall, as required by 42 CFR § 93.108 : (1) limit disclosure of the identity of respondents and complainants to those who need to know 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 to carry out a research misconduct proceeding. The DO should use written

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

D. Protecting complainants, witnesses, and committee members

Researchers may not retaliate against complainants, witnesses, or committee members. Researchers should immediately report any alleged or apparent retaliation against complainants, witnesses, or committee members to the DO, 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.

E. Protecting the Respondent

As requested and as appropriate, the DO and other STA officials 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 research misconduct is found.[10]

F. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the DO 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 PHS supported research process. In the event of such a threat, the DO will, in consultation with other STA officials and ORI, take appropriate interim action to protect against any such threat.[11] Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or the responsibility for handling federal funds and equipment, additional review of research data and results, or delaying publication. The DO 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:

- The health or safety of the public is at risk, including an immediate need to protect human or animal 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.[12]

V. Notifying the Federal Office and Conducting the Assessment and Inquiry

A. Notify ORI or other applicable federal agency office in charge of research misconduct.

Upon receiving an allegation of research misconduct, the DO will immediately contact the Office of Research Integrity (ORI) at (240) 453-8400. In consultation with ORI, the DO will develop and implement a process consistent with the regulation at 42 CFR Part 93 to fully explore the allegation or evidence of misconduct involving PHS supported research or research activities. This may entail ORI/HHS taking primary responsibility for conducting the inquiry and/or investigation.

B. Sequestration of Research Records

On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the DO 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 several 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.[13] The DO may consult with ORI for advice and assistance in this regard.

VI. 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 DO must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that the 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.[14]

VII. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of STA's responsibilities under 42 CFR Part

93.

If the respondent, without admitting to the misconduct, elects to resign his or her position after STA receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the DO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the DO must, at the respondent's request, undertake all reasonable and practical efforts to restore the respondent's reputation.[15] Depending on the particular circumstances and the views of the respondent, the DO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any actions by STA to restore the respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses and Committee Members

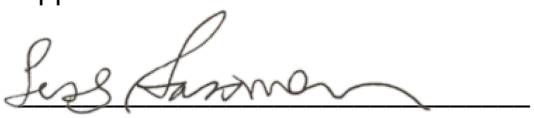
During the research misconduct proceeding and upon its completion, regardless of whether STA or ORI determines that research misconduct occurred, the DO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.[16] The DO will determine, after consulting with the DO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The DO is responsible for implementing any steps the DO approves.

D. Allegations Not Made in Good Faith

If relevant, the DO will determine whether the complainant’s allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith, they will determine whether any

administrative action should be taken against the person who failed to act in good faith.

Approved:



Lisa Gassman, Chief Executive Officer

03/07/2024

Date

NOTES:

[1] 42 CFR § 93.214

[2] 42 CFR § 93.102

[3] 42 CFR §§ 93.304(c), 93.307(b)

[4] 42 CFR §§ 93.304(e), 93.307(f)

[5] 42 CFR § 308(a)

[6] 42 CFR § 310(c)

[7] 42 CFR § 310(g)

[8] 42 CFR § 310(g)

[9] 42 CFR §§ 93.304(f), 93.312(a)

[10] 42 CFR § 93.304(k)

[11] 42 CFR § 93.304(h)

[12] 42 CFR § 93.318

[13] 42 CFR §§ 93.305, 93.307(b)

[14] 42 CFR § 93.316(a)

[15] 42 CFR § 93.304(k)

[16] 42 CFR § 93.304(l)

Appendix A: Designated Misconduct Policy and Procedures Official Responsibilities

I. General

The Designated Misconduct Policy and Procedures Official (DO) has lead responsibility for ensuring that STA:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

- Has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to ORI, as required by 42 CFR Part 93.

- Complies with its written policies and procedures and 42 CFR Part 93 requirements.

- Informs its researchers who are subject to 42 CFR Part 93 about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures.

- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS-supported research process.

II. Notice and Reporting to ORI and Cooperation with ORI

The DO has lead responsibility for ensuring that STA:

- Files an annual report with ORI containing the information prescribed by ORI.

- Sends to ORI with the annual report such other aggregated information as ORI may prescribe on STA's research misconduct proceedings and STA's compliance with 42 CFR Part 93.

- Notifies ORI immediately if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, HHS resources or interests are threatened, research activities should be suspended, there is 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, STA believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed.

- Cooperates fully with ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under STA's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

III. Research Misconduct Proceeding

A. General

The DO is responsible for:

- Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.

- Taking all reasonable and practical steps to ensure the cooperation of respondents and other researchers with research misconduct proceedings, including, but not limited to their providing information, research records and evidence.

- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and STA policy.

- Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.

- Keeping STA CEO and others who need to know apprised of the progress of the review of the allegation of research misconduct.

- In cooperation with other STA officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other researchers.

- Making all reasonable and practical efforts, if requested and as appropriate, 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.

- Assisting the STA CEO in implementing his/her decision to take administrative action against any complainant, witness, or committee member determined by the STA CEO not to have acted in good faith.

- Maintaining records of the research misconduct proceeding, as defined in 42 CFR § 93.317, in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.

- Ensuring that administrative actions taken by STA and ORI are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.