WSCR POLICIES AND PROCEDURES

DEALING WITH ALLEGATIONS OF RESEARCH MISCONDUCT

Purpose

The purpose of this policy is to provide guidelines for responding to allegations of research misconduct. Any violation of professional standards in the conduct of research by a research investigator is a matter for inquiry and if determined appropriate, investigation, and may result in disciplinary action.

Western States Cancer Research (WSCR) NCORP accepts its obligation to promote research integrity by fostering a research environment that encourages the responsible conduct of research and deals forthrightly with reports of possible research misconduct. WSCR research personnel assure quality and integrity in research primarily by internal and external monitoring and audits, and peer review.

WSCR maintains an active Assurance with the Office of Research Integrity (ORI). WSCR's Chief Executive Officer/Executive Director ordinarily serves as WSCR's Institutional Certifying Official and files the annual report regarding research misconduct proceedings, as required.

This policy is written to protect PHS funds to comply with:

- Public Health Service (PHS) regulation 42 CFR Part 93, *Public Health Service Policies on Research Misconduct*; and
- Federal Policy on Research Misconduct issued by the Office of Science and Technology Policy

This policy ensures that research misconduct involving PHS-supported research will be evaluated and reported to the Office of Research Integrity in compliance with 42 CFR 93.

These procedures will be followed when an allegation of possible misconduct in research is received. Any deviation from these standard procedures is to be approved in advance by Western States Cancer Research (WSCR) NCORP Board of Directors, if possible. Material deviations from this policy will be documented, justified, and approved by the Institutional Deciding Official or Board designee, if immediate action is required to protect participants, federal funds, evidence, or public interest. Material deviations from this policy involving PHS-supported research will be reported to ORI when required by 42 CFR Part 93.

This policy applies to all research conducted under WSCR's oversight, including PHS-supported and privately sponsored studies. For PHS-supported studies, WSCR complies with PHS regulation 42 CFR Part 93, including the revised requirements applicable to allegations received on or after January 1, 2026, and reports to ORI as required. For privately sponsored research, WSCR follows the same internal

assessment, inquiry, and investigation procedures to maintain research integrity, but is not required to report to ORI.

The procedures will ensure fair treatment of the subject of an assessment, inquiry, or investigation.

Because WSCR is a small institution, if WSCR lacks sufficient non-conflicted personnel or subject-matter expertise to conduct any phase of a research misconduct proceeding, WSCR may consult ORI and/or retain qualified external reviewers, consultants, or counsel to support a fair, competent, objective, and conflict-free process.

Scope

These policies and procedures apply to all research and research-related activity, regardless of the sponsor, that is conducted in whole or in part within Western States Cancer Research NCORP. ***For the entirety of this policy, where strictly privately funded research is involved, assessments, inquiries, and investigations will be handled internally, according to this policy, but without mandatory notification to external federal agencies, including ORI, unless otherwise required. For strictly privately funded research, external notification to private authorities, including the study sponsor and/or IRB of record, may be required under contractual or ethical obligations. WSCR will follow sponsor and IRB reporting requirements for privately funded studies.***

For PHS-covered allegations, WSCR will apply the time limitations in 42 CFR 93.104. Generally, Part 93 applies only to research misconduct occurring within six years of the date HHS or WSCR receives the allegation, unless an exception applies. WSCR will document determinations regarding applicability of the six-year limitation and any exception.

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community;
- The misconduct be committed intentionally, knowingly, or recklessly; and
- The allegation is proven by a preponderance of evidence.

The response to an allegation of research misconduct will usually consist of several phases including:

- Assessment: Discreet initial review to determine whether an allegation warrants an inquiry;
- Inquiry: Preliminary information-gathering and fact-finding to determine whether an investigation is warranted;
- Investigation: The formal development and examination of a factual record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies; and
- Adjudication/Final Institutional Decision: Institutional Deciding Official's

review and final written determination.

- ORI will be notified immediately of any special circumstances, particularly when the health and safety of study subjects is at risk. Full list is available at 42 CFR 93.305(g).

Definitions

Allegation: Any written or oral statement or other indication of possible research misconduct made to the Principal Investigator, Chief Executive Officer/Executive Director, WSCR Board of Directors, or other WSCR employee or affiliate.

Chief Executive Officer/Executive Director (CEO): The senior executive official responsible for the overall management, operations, and administration of WSCR. For purposes of this policy, the Chief Executive Officer/Executive Director ordinarily serves as WSCR's Institutional Deciding Official and Institutional Certifying Official unless conflicted, unavailable, or otherwise unable to serve. The Chief Executive Officer/Executive Director may take or authorize administrative, operational, employment, or protective actions as appropriate, consistent with this policy and applicable law.

Complainant: Anyone who in good faith (1) makes an allegation that WSCR, or a researcher employed by one of the organizations that participates in, has engaged in, or failed to respond adequately to an allegation of research misconduct or (2) cooperates with an investigation of an allegation.

Conflict of interest: The real or apparent interference of one person's interest with another, where there may be potential bias because of a prior or existing personal or professional relationship.

Fabrication: Making up data or results and recording or reporting them.

Falsification: Manipulating research materials, equipment, or processes; changing or omitting data or results such that the research is not accurately represented in the research record.

Good faith allegation: An allegation of research misconduct made by a complainant who honestly believes that research misconduct may have occurred. A good faith allegation need not be objectively made, nor be subsequently verified, to have been made in good faith. However, a complainant who recklessly disregards evidence that disproves an allegation has not made the allegation in good faith.

Inquiry: An initial information gathering and fact-finding process to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

Institutional Certifying Official (ICO): The institutional official responsible for certifying the ORI assurance/annual report. The ICO may also submit formal notices, reports, requests, and institutional records to ORI in coordination with the RIO and IDO, as appropriate. WSCR's CEO will ordinarily serve in this role unless conflicted or unavailable.

Institutional Deciding Official (IDO): The institutional official responsible for final institutional determination after an investigation, upon recommendation from the Research Integrity Subcommittee. WSCR's CEO will ordinarily serve in this role. The Board Chair or other qualified individual may serve as IDO if the CEO is conflicted or unavailable. The IDO must not have served as the RIO, inquiry reviewer, Research Integrity Subcommittee member, witness, complainant, respondent, or substantive advisor for a particular investigation.

Institutional Record: The complete record of WSCR's research misconduct proceeding, including assessment documentation, inquiry documentation, investigation records, sequestered evidence, interview recordings/transcripts, notices, respondent and complainant comments, the inquiry report, the investigation report, the Institutional Deciding Official's final decision, ORI communications, documentation of institutional actions, and any other records required to be maintained under 42 CFR Part 93.

Investigation: The formal examination and evaluation of all relevant facts to determine if misconduct has occurred and, if so, the responsible person and the seriousness of the misconduct.

Office of Research Integrity (ORI): The independent entity within the U.S. Department of Health and Human Services reporting to the Secretary of Health and Human Services. The ORI is responsible for protecting the integrity of Public Health Service's extramural and intramural research programs.

Plagiarism: Appropriation of another's ideas, processes, results, or words without giving appropriate credit.

PHS regulation: The PHS regulation codified at 42 CFR Part 93, *"Public Health Service Policies on Research Misconduct."*

Privately Sponsored Research: Research conducted under the sponsorship of non-federal, private entities, not subject to mandatory reporting to ORI, but governed by this policy and WSCR's internal standards of research integrity.

Public Health Service (PHS): Part of the Department of Health and Human Services (DHHS) of the federal government. Includes the NIH and NCI; NCORP is an NCI-supported program.

Regulatory and Compliance Director: The WSCR official responsible for overseeing regulatory compliance, research integrity processes, regulatory document and essential-record standards, and compliance support for WSCR. For purposes of this policy, the Regulatory and Compliance Director ordinarily serves as WSCR's Research Integrity Officer unless conflicted, implicated, unavailable, a material witness, or otherwise unable to serve.

Research Integrity Officer (RIO): The institutional official responsible for receiving allegations; conducting or coordinating initial assessments; preserving evidence; administering the research misconduct process; preparing or coordinating required notices, reports, and communications with ORI; and maintaining the institutional record. The Regulatory and Compliance Director ordinarily serves as RIO unless conflicted, implicated, unavailable, a material witness, or otherwise unable to serve.

Research Integrity Subcommittee: A subcommittee for the purpose of investigating allegations of research misconduct. Additional context and requirements are noted in the institutional roles section.

Research misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion. *This definition applies to both PHS-supported and privately sponsored research.*

Research record: Record of data or results that embody the facts resulting from scientific inquiry and includes, but is not limited to all individual patient information relating to the research, and study communications, both physical and electronic.

Respondent: The person against whom an allegation of research misconduct is directed, or the person who is the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

Retaliation: Any response by WSCR or an employee that adversely affects the employment or other status of a complainant, witness, committee member, or other individual who, in good faith (1) has made an allegation of research misconduct or inadequate institutional response, or (2) has cooperated in good faith with an investigation of such allegation.

Whistleblower: See definition of Complainant.

Responsibilities & Institutional Roles

Institutional Roles

- **Research Integrity Officer (RIO) –** *official role per 42 CFR Part 93*. The institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct i.e. receives allegations, conducts assessment, oversees records sequestration, manages inquiry/investigation process. The Regulatory and Compliance Director will ordinarily serve in this role, unless conflicted. If Regulatory and Compliance Director is conflicted, implicated, unavailable, a material witness, or otherwise unable to serve, this role may be an external compliance consultant or other designee appointed by the CEO or Board of Directors.
- **Institutional Deciding Official (IDO) –** *official role per 42 CFR Part 93*. The institutional official responsible for final institutional determination after an investigation, upon recommendation from the Research Integrity Subcommittee. WSCR's CEO will ordinarily serve in this role. The Board Chair or other qualified individual may serve as IDO if the CEO is conflicted or unavailable. The IDO must not have served as the RIO, inquiry reviewer, Research Integrity Subcommittee member, witness, complainant, respondent, or substantive advisor for a particular investigation.
- **Institutional Certifying Official (ICO) –** *official role per 42 CFR Part 93*. The institutional official responsible for certifying the ORI assurance/annual report. The ICO may also submit formal notices, reports, requests, and institutional records to ORI in coordination with the RIO and IDO, as appropriate. WSCR's CEO will ordinarily serve in this role unless conflicted

or unavailable.

- **Research Integrity Subcommittee –** Three-person committee responsible for conducting the investigation by development of factual record and providing recommendation of misconduct findings to the Institutional Deciding Official. Members are appointed by the CEO/IDO and Regulatory and Compliance Director/RIO, but the IDO and RIO may not serve on the Subcommittee. Members may be approved by WSCR's Board of Directors, or notification to Board Chair may be provided, depending on the situation. Members of the Board of Directors may serve on the Subcommittee if they:
    - Are not subjects of or witnesses in the investigation; and,
    - Have no conflicts of interest of any type with the complainant, respondent, witnesses, study, sponsor, site, or allegation; and,
    - Will be recused from any board discussion or vote concerning administrative actions of the respondent, sanctions, funding repayment, corrective action, or other administrative response to the matter.

  The committee may include qualified external experts or consultants when necessary to ensure adequate expertise, independence, or absence of real or apparent conflicts of interest with the respondent or case in question.

Complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation. The complainant will have the right to:

- Be interviewed by the inquiry and investigation committees;
- Review portions of the inquiry and investigation reports pertinent to that testimony, and provide comments;
- Be informed of the results of the inquiry and investigation; and
- Be protected from retaliation.

Western States Cancer Research Board of Directors:

- Make sufficient resources (staff support, meeting space, etc.) available to the Institutional Deciding Official and Research Integrity Officer to carry out their responsibilities under this SOP.
- Support and enable training in the responsible conduct of research.
- In a situation involving the allegation or determination of PHS-supported research misconduct, collaborate with the WSCR's Chief Executive Officer/Executive Director to ensure that interim administrative actions are taken, as appropriate, to protect federal funds, and that the purposes of federal financial assistance are carried out.

The Regulatory and Compliance Director/RIO:

- The Regulatory and Compliance Director is qualified and responsible for ensuring procedural compliance and maintaining impartiality; is knowledgeable about research; and is sensitive to: the demands made on those who conduct research, those accused of misconduct, those who report apparent misconduct in good faith.

- Has the authority to request and receive documents necessary to carry out this policy and procedure.

- In the event of an inquiry, and possibly before, the Regulatory and Compliance Director/RIO will report preliminary findings to the CEO, acting as IDO and/or ICO, as applicable. Preliminary findings of misconduct involving PHS-supported research will be reported to the ORI as required by regulation.

- WSCR will keep the ORI apprised of any development that may affect current or potential DHHS funding for the individual(s) under investigation.

- The Regulatory and Compliance Director/RIO, along with the CEO, acting as ICO and/or IDO, will work together to keep ORI apprised of any development relating to the appropriate use of federal funds and the protection of public interest.

- All points above apply to the RIO if the Regulatory and Compliance Director cannot serve in the capacity of RIO. Policy references to the "Regulatory and Compliance Director/RIO" must be understood as including an alternative RIO.

The Respondent:

- Will be informed of the allegation and notified in writing of the final determination and resulting action.

- The respondent will have the opportunity to be interviewed by, and present evidence to, the inquiry and investigation committees, and to review and respond to the inquiry and investigation reports to the extent consistent with this policy.

- The respondent is responsible for maintaining confidentiality, and for cooperating with the inquiry or investigation committees.

Miscellaneous:

- Policy references to the "CEO/IDO" or "CEO/ICO" must be understood as referring to the individual serving in the applicable role if the CEO cannot serve.

- Protections against retaliation and appropriate confidentiality protections also apply to witnesses, committee members, and other individuals who cooperate in good faith with an assessment, inquiry, or investigation.

Procedures

Educating Staff on Research Misconduct

This policy will be discussed with every new member of WSCR's staff at the time of hire.

WSCR will inform institutional members of this policy and WSCR's commitment to compliance with this policy. WSCR will make this policy publicly available on its website or through another publicly accessible method in accordance with 42 CFR 93.302.

Confidentiality and Information Sharing

To protect the integrity of the process and the reputations of all individuals involved, information related to allegations, inquiries, and investigations will be shared internally on a strict need-to-know basis.

- **During an assessment and inquiry**, knowledge of the allegation will be limited to the Regulatory and Compliance Director/RIO, Chief Executive Officer/Executive Director/IDO, and other individuals deemed necessary to conduct the assessment and inquiry.

- **If an investigation is initiated**, additional individuals may be informed, but only to the extent necessary to secure evidence, interview witnesses, or conduct a fair and thorough investigation.

- **Members of the WSCR Board of Directors** will be notified if an allegation proceeds beyond the inquiry stage, or earlier if necessary for legal, financial, or patient safety reasons.

- At all times, efforts will be made to protect the confidentiality of both the complainant and the respondent, consistent with ensuring the integrity of the review process and protecting public health and safety.

- Unauthorized disclosure of information related to a research misconduct inquiry, investigation, or proceeding may be grounds for disciplinary action.

Reporting Misconduct

- All employees or individuals associated with WSCR are required to report observed, suspected, or apparent misconduct in research to the Regulatory and Compliance Director/RIO. If an individual is unsure whether a suspected incident falls within the definition of misconduct, they should consult with the Regulatory and Compliance Director/RIO to discuss, confidentially and preliminarily, the suspected misconduct. *If the allegation involves the Regulatory and Compliance Director/RIO, the allegation should be reported to the CEO/Executive Director, Board Chair, or another non-conflicted institutional official.*

- Upon receiving an allegation of research misconduct, the Regulatory and Compliance Director/RIO will promptly conduct a discreet assessment to determine whether the allegation is sufficiently credible and specific so that

potential evidence may be identified to warrant an inquiry. The Regulatory and Compliance Director/RIO will also determine whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of misconduct in research.

- The employee will be advised about the procedure to report allegations. If the circumstances described by the individual do not meet the definition of research misconduct, the Regulatory and Compliance Director/RIO will refer the individual or allegation to other individuals to resolve the problem and will retain documentation for later review.

- After determining that an allegation falls within the definition of misconduct in research, the Regulatory and Compliance Director/RIO will initiate an inquiry. All relevant research records and materials will be sequestered in such a manner as deemed appropriate.

- WSCR's NCORP staff and Investigators will cooperate in the review of allegations and the conduct of assessments, inquiries, and investigations.

- The Regulatory and Compliance Director/RIO will provide guidance and exercise oversight to the extent reasonable in the treatment of individuals who bring allegations of misconduct and/or inadequate institutional response, or who cooperate in inquiries or investigations. If the complainant requests anonymity, an effort will be made to honor the request within applicable policies, regulations, and state and local laws. Diligent efforts will be undertaken to protect complainants from retaliation as a result of their involvement in a complaint.

- Assessments, inquiries, and investigations will be conducted in a manner that will ensure fair treatment to the subject(s) of the assessment, inquiry, or investigation. The assessments, inquiries, and investigations will be conducted to ensure confidentiality consistent with protecting public health and safety.

- The Regulatory and Compliance Director/RIO will take reasonable steps to assure that those making allegations in good faith or cooperating with an assessment, inquiry, or investigation will not be retaliated against in the terms and conditions of their employment or other status.

Assessment

The purpose of an assessment is to evaluate if an allegation:

- Falls within the definition of research misconduct; and
- Is applicable within the criteria of 42 CFR Part 93; and
- Is sufficiently credible and specific so that potential evidence may be identified.

If these criteria are met, the Regulatory and Compliance Director/RIO will document the assessment, promptly sequester relevant research records and evidence, and initiate an inquiry. If the criteria are not met, the Regulatory and Compliance Director/RIO will retain sufficiently detailed documentation to permit

later review, if required.

Inquiry

The purpose of an inquiry is to evaluate a situation to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose of the inquiry is not to reach a conclusion as to whether misconduct occurred or who was responsible.

- If the Regulatory and Compliance Director/RIO believes that an inquiry is warranted, the Regulatory and Compliance Director/RIO will proceed to conduct the inquiry. To the extent possible, the Regulatory and Compliance Director/RIO must not have conflicts of interest in the case, must be unbiased, and have appropriate qualifications to evaluate the issues raised. If this is not the case, the Chief Executive Officer/Executive Director/IDO or Board of Directors will appoint a qualified individual to conduct the inquiry.

- Per revised part 93, the Regulatory and Compliance Director/RIO will make a good faith effort to provide written notice to the respondent at the beginning of the inquiry. Only allegations specific to that respondent will be included.

- The purpose of the inquiry is to evaluate the facts to determine whether there is sufficient evidence of misconduct to warrant an investigation.

- The inquiry process will normally involve interviewing the complainant, respondent, and key witnesses, and examining relevant research records and materials.

- The inquiry will normally be completed, and if appropriate, a written report will be prepared no more than 90 calendar days following its initiation.

- The written inquiry report will state:
  - respondent/complainant names, professional aliases (if any), and positions,
  - description of the allegations of misconduct,
  - PHS support (if applicable), including grant numbers, applications, etc.,
  - inventory of sequestered records,
  - how record sequestration was conducted,
  - transcripts of any transcribed interviews,
  - timeline and procedural history,
  - any analyses,
  - basis for recommending an investigation and/or basis for allegations not investigated,
  - comments by respondent(s) or complainant(s),
  - and institutional actions (if applicable), including communications with external organizations.

- WSCR will provide the respondent(s) with a copy of the inquiry report, and will

grant the respondent(s) the opportunity to review and comment on the report. WSCR may redact or limit disclosure of information identifying complainants, witnesses, or research participants to the extent permitted by law and consistent with a fair, competent, objective, and thorough proceeding.

- The Regulatory and Compliance Director/RIO will recommend to the CEO/IDO whether an investigation is necessary, whether the matter should be dropped, or whether some other appropriate action is indicated, based on the following:
  - There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct; and
  - Preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance.

- The CEO/IDO will make the final determination whether an investigation will be conducted.

- Findings of research misconduct cannot be made at the inquiry stage.

Investigation

- If findings from the inquiry provide sufficient basis for investigating, a Research Integrity Subcommittee will be appointed, and the process initiated within 30 days of the completion of the inquiry and determination that an investigation is warranted.

- The purpose of an investigation is to examine and evaluate all relevant facts to determine whether research misconduct has been committed and, if so, to determine the responsible person and the seriousness of the misconduct.

- The CEO/IDO and the Regulatory and Compliance Director/RIO will appoint at least three members, other than themselves, to the Research Integrity Subcommittee. These individuals should not have any real or apparent conflicts of interest with the respondent or the case in question and must have the necessary expertise to examine the evidence, interview the witnesses, and conduct the investigation.

- The Regulatory and Compliance Director/RIO will define the subject matter of the investigation in a written charge to the Research Integrity Subcommittee.

- Interviews should be conducted of all complainant(s) and respondent(s), as well as individuals who may have information regarding key aspects of the allegations, including witnesses. If this is not possible for any individual, this should be explained in the investigation report.

- All interviews will be transcribed and recorded. Exhibits shown or discussed during interviews will be identified and numbered. Complete transcripts of these interviews will be prepared, provided to the interviewed party for comment or revision, and included as part of the investigation file.

- An investigation should normally be completed, including transmission of the institutional record and final decision to ORI, within 180 days of its initiation. The

investigation will include preparing the report of findings, making the report available for comment by the subjects of the investigation, and submission of the report and recommendations to the Institutional Deciding Official. The Board of Directors may be informed as necessary for governance, legal, financial, funding, or employment-related action, but Board involvement must not compromise the independence of the inquiry, investigation, or final determination.

- The respondent(s) will be given a draft copy of the investigation report, a copy of the records and evidence the committee considered or relied upon, and an opportunity to comment on the report. Respondent(s)' comments are due within 30 days. WSCR will take reasonable steps to protect the identity of the complainant(s), witnesses, and research participants to the extent possible, consistent with a thorough, competent, objective, and fair research misconduct proceeding and as allowed by law. If WSCR elects to provide the complainant(s) with an opportunity to comment, the complainant(s) may be provided only those portions of the draft investigation report that address their role, statements, or testimony. The report may be further modified as appropriate in light of the comments of the complainant and respondent.

- The Research Integrity Subcommittee will prepare a final investigation report per 42 CFR 93.313 *"Investigation report",* and recommended findings of whether misconduct has occurred, for each allegation and each respondent. The Subcommittee will also recommend sanctions or administrative actions to be taken with the respondent.

- The Institutional Deciding Official will review the report, respondent comments, institutional record, and any committee recommendations, and will issue the final institutional decision. The final decision of misconduct will be made by the Institutional Deciding Official, who may not be involved in the investigation or a member of the Research Integrity Subcommittee.

Notification and Reporting Requirements to the Office of Research Integrity (ORI)

- For PHS-supported research, the decision to initiate an investigation will be reported in writing to WSCR's Board of Directors and the ORI. This written notice is to be submitted on or before the date the investigation begins. WSCR will provide to ORI the written inquiry report, which must contain the elements required by 42 CFR 93.309.

- For allegations of research misconduct involving PHS-supported research, after the IDO issues the final institutional decision, the CEO/ICO, in coordination with the RIO and IDO as appropriate, will submit the final investigation report, final institutional decision, and institutional record to ORI as required by 42 CFR Part 93. The final investigation report will contain the elements required by 42 CFR 93.313, including, as applicable:
    - Policies and procedures under which the investigation was conducted;
    - Description of how and from whom information was obtained relevant to the investigation;
    - Any significant deviation from the policies and procedures

- The findings, and explanation for the basis of the findings;
- The actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct; and
- Description of any sanctions taken by WSCR NCORP

- If an inquiry or investigation involving PHS-supported research is to be terminated for any reason without completing all institutional and federal requirements, the CEO/ICO, in coordination with the RIO and IDO as appropriate,will submit a report of the planned termination to ORI and include the reasons for the termination. The investigation will resume should ORI deem it necessary.

- If the investigation cannot be completed in 180 days, the CEO/ICO, in coordination with the RIO and IDO as appropriate, will submit a request for extension to ORI. The request for extension will include an interim report on the progress to date and an estimate for the date of completion.

- When an admission of research misconduct is made, the CEO/ICO, in coordination with the RIO and IDO as appropriate, will contact the ORI immediately for consultation and advice.

- WSCR will not accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval by ORI.

- The termination of employment of the respondent by resignation or otherwise, or withdrawing as a WSCR Investigator, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures.

- The process will proceed if the respondent, without admitting to the misconduct, elects to resign their position prior to the initiation of an inquiry, but after an allegation has been reported.

- If the respondent refuses to participate in the process after resignation, the Research Integrity Subcommittee will use its best efforts to reach a conclusion concerning the allegations. The respondent's failure to cooperate will be noted in the report, as well as its effect on the review of the evidence.

- Diligent efforts will be undertaken to restore the reputation of the respondent if no finding of research misconduct is made. Persons who have been interviewed or otherwise informed of the charge will be notified in writing that the charges have been dropped. Respondents should be consulted regarding other actions that might be taken to restore their reputations.

- For PHS-supported research, the CEO/ICO, in coordination with the RIO and IDO as appropriate, will immediately notify the ORI if it is determined at any stage of the inquiry or investigation that any of the following special circumstances exist. This list is not exhaustive – see 42 CFR 93.305(g) for a complete list. For privately funded research, private authorities, including IRB and study sponsor, will be notified if any of the following conditions exist:

- There is an immediate health hazard involved;
- There is an immediate need to protect funds or equipment;
- There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as their co-investigators and associates, if any;
- It is probable that the alleged incident is going to be reported publicly; or
- There is a reasonable indication of possible criminal violation.

Coordination with Human Subject Protection, IRB, Sponsor, and NCI Reporting

The PI may be notified or consulted when necessary for participant safety, study conduct, NCI/NCORP reporting, protection of federal funds, institutional operations, or anything that may be relevant for study oversight, provided the PI has no conflict of interest and the disclosure is limited to the minimum necessary information. PI acknowledgement may be included in the report to ORI.

When human-subject protection reporting may be required, WSCR will follow the applicable IRB of record's reporting requirements and any applicable institutional, sponsor, NCI, NCI-CIRB, OHRP, FDA, HIPAA/privacy, and protocol-specific reporting obligations.

Retention of Records

- After completion of a case and all related actions, the RIO, in coordination with the IDO and/or ICO, as applicable, will prepare a file of all documents and other materials furnished to the Research Integrity Subcommittee. This will include assessment documentation, inquiry documentation, the institutional record including the investigation report and all sequestered evidence in accordance with 42 CFR 93.318.

    - For PHS-covered allegations, WSCR will retain assessment documentation, inquiry documentation, the institutional record, and all sequestered evidence in accordance with 42 CFR 93.318. The file will be retained for seven years from the date the case was closed, or from the date that ORI completed its review of the case, whichever is later

    - For non-PHS matters, WSCR will retain assessment documentation that does not proceed to inquiry for at least one year unless longer retention is required by sponsor, IRB, institutional, legal, or operational requirements.

Interim Administrative and Employment Actions

Nothing in this policy limits WSCR's authority to take interim administrative, operational, employment, corrective, or protective action at any point during an assessment, inquiry, investigation, or related proceeding. Such actions may include, but are not limited to, removal from a study or study-related duties, restriction or suspension of system access, reassignment, administrative leave, increased supervision, required retraining, notification to affected sites or investigators when necessary, or termination of employment.

Interim or employment actions may be based on documented employment, operational, compliance, participant-safety, data-integrity, PI/site relationship, trust, performance, or business reasons, even if a final institutional finding of research misconduct has not yet been made.

Unless and until a final institutional decision has been issued under this policy, WSCR will not characterize such action as based on a final finding of research misconduct. Taking interim or employment action does not terminate, replace, or predetermine the research misconduct proceeding. For PHS-supported research, WSCR will continue the proceeding and meet applicable ORI reporting and record-retention obligations regardless of whether the respondent remains employed by or affiliated with WSCR.

Sanctions and Administrative Actions

- WSCR's Board of Directors will impose appropriate sanctions on individuals when an allegation of misconduct has been substantiated, based upon recommendations from the Research Integrity Subcommittee. If a member of the Board of Directors is a member of the Research Integrity Subcommittee, they may not be involved in this imposition of sanctions or disciplinary actions.

- If determined that the alleged misconduct is substantiated by the findings, the following actions are decided upon:
    - Restitution of funds to any sponsoring agency, as appropriate.
    - Withdrawal or correction of all data emanating from the research in question.
    - Removal from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or termination of employment.

- Employment, operational, or protective actions taken before a final institutional decision are addressed under "Interim Administrative and Employment Actions" and are not dependent on a final finding of research misconduct.

Signatures of Approval

Signed by:
Lisa Switzer
Signer Name: Lisa Switzer
Signing Reason: I approve this document
Signing Time: 29-Apr-2026 | 3:22:44 PM MDT
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29-Apr-2026

Lisa A. Switzer | CEO & Executive Director **Date**

Signed by:
William Coffey
Signer Name: William Coffey
Signing Reason: I am the author of this document
Signing Time: 29-Apr-2026 | 3:12:13 PM MDT
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29-Apr-2026

William A. Coffey | Regulatory & Compliance Director **Date**

Certificate Of Completion

Envelope Id: E2E92353-3D38-8906-823D-B1E639C301C2
Status: Completed
Subject: Complete with Docusign: WSCR Scientific Misconduct Policy_29Apr2026_final.pdf
Source Envelope:
Document Pages: 16
Signatures: 2
Envelope Originator:
Certificate Pages: 5
Initials: 0
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Record Tracking

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wcoffey@westernstatesncorp.org
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Lisa Switzer lswitzer@westernstatesncorp.org CEO/ED Western States Cancer Research NCORP- Part 11 Security Level: Email, Account Authentication (Required), Logged in	Signed by: Lisa Switzer Signer Name: Lisa Switzer Signing Reason: I approve this document Signing Time: 29-Apr-2026 | 3:22:44 PM MDT A2908C937CC7428E8028E6EA96231497 Signature Adoption: Pre-selected Style Signature ID: A2908C93-7CC7-428E-8028-E6EA96231497 Using IP Address: 65.144.97.218 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 29-Apr-2026 | 15:11 Resent: 29-Apr-2026 | 15:19 Resent: 29-Apr-2026 | 15:20 Resent: 29-Apr-2026 | 15:20 Viewed: 29-Apr-2026 | 15:22 Signed: 29-Apr-2026 | 15:22
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William Coffey wcoffey@westernstatesncorp.org Regulatory Coordinator I Western States Cancer Research NCORP Security Level: Email, Account Authentication (Required), Logged in	Signed by: William Coffey Signer Name: William Coffey Signing Reason: I am the author of this document Signing Time: 29-Apr-2026 | 3:12:13 PM MDT 53AA1C328BF343D297612DD3267855ED Signature Adoption: Pre-selected Style Signature ID: 53AA1C32-8BF3-43D2-9761-2DD3267855ED Using IP Address: 65.144.97.218 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I am the author of this document	Sent: 29-Apr-2026 | 15:11 Viewed: 29-Apr-2026 | 15:11 Signed: 29-Apr-2026 | 15:12
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Carley Sklenar csklenar@westernstatesncorp.org Western States Cancer Research NCORP Security Level: Email, Account Authentication (Required) **Electronic Record and Signature Disclosure:** Accepted: 07-Jul-2023 | 13:20 ID: 86c57b4d-c32d-4f56-8733-198109392342	COPIED	Sent: 29-Apr-2026 | 15:11
Kayla Graves kgraves@westernstatesncorp.org Western States Cancer Research NCORP Security Level: Email, Account Authentication (Required) **Electronic Record and Signature Disclosure:** Not Offered via Docusign	COPIED	Sent: 29-Apr-2026 | 15:11

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Envelope Sent	Hashed/Encrypted	29-Apr-2026 | 15:11
Certified Delivered	Security Checked	29-Apr-2026 | 15:11
Signing Complete	Security Checked	29-Apr-2026 | 15:12
Completed	Security Checked	29-Apr-2026 | 15:22

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