# Research Misconduct

## Policy & Procedural Manual

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Research Misconduct Policy

Policy Owner: Mary Clem
Department: Office of Research and Sponsored Programs

1.0 General Policy
Emphasizing intellectual inquiry and social responsibility, St. Catherine University strives to foster, support and facilitate a scholarly community committed to quality, ethical teaching and learning experiences that engage researchers and scholars, while contributing to the health and well-being of society.

The University, its researchers and scholars recognize research integrity is essential within the liberal arts and professional disciplines, and that failure to engage in ethical research and scholarship or to report misconduct, undermine a central aim of the academic enterprise: the pursuit of knowledge. Whether in the lab, clinic, archive, classroom or community, St. Kate’s researchers and scholars uphold key values necessary to advance discipline-based knowledge: honesty, open-mindedness, avoidance of error, accountability, respect for intellectual property, responsible authorship, the protection of human and animal subjects, responsible mentoring, respectful collaboration, and social responsibility.

Regulations and policies do not always provide clear guidelines on ethical and responsible behavior. Researchers and scholars must think critically, act with respect and fairness, be socially conscientious, make ethical decisions, and recognize the critical importance of open dialogue as they navigate and apply a maze of often-conflicting rules and guidelines. The University must also provide the policies, education, staff and infrastructure to form the foundation of an environment that upholds these important values.

Scope
In line with these values and all applicable federal regulations governing the conduct of research, including but not limited to 42 CFR Parts 93, this document provides the University’s policy and procedures guiding response to allegations of research misconduct involving University faculty, staff and students, as well as others engaged in research affiliated with the University.

2.0 Policy Definitions
Research Misconduct does NOT include honest error or differences in interpretations or judgments of data, but does consist of the following prohibited acts:
- Fabrication of data. Fabrication is making up data or results and recording or reporting them.
- Falsification of data, research procedures, or data analysis. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism - the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

A person is found to commit Research Misconduct encompassing their research and scholarship when they:
- Intentionally engage in a prohibited act: plagiarism, falsification, fabrication, misappropriation, retaliation or fraud. Intentionally does not require one to be aware that their action is a violation of the Research Misconduct Policy;
- **Knowingly** engage in actions that are practically certain to result in a prohibited act, such as plagiarism, falsification, fabrication, misappropriation, retaliation or fraud; and
- **Recklessly** and consciously disregard a substantial and unjustifiable risk that one’s action will result in the prohibited act.

**Office of Research Integrity (ORI)** oversees research integrity activities on behalf of the U.S. Department of Health and Human Services and is the regulatory body to which the University is accountable for reporting Research Misconduct.

**Complainant** is the person responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation.

**Respondent** is the individual charged with research misconduct and is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation.

**Deciding Official (DO)** is a University leader responsible for making final determinations on research misconduct allegations, determining and performing related administrative actions, appointing representatives to assess allegations or serve on Inquiry or Investigation Committees and communicating findings and plans with the Office of Research Integrity. The DO cannot be the same individual as the Research Integrity Officer and should have no prior involvement in the inquiry, investigation or allegation assessment.

**Research Integrity Officer (RIO)** is responsible for assessing and managing the process related to allegations of research misconduct; facilitating the Investigation Committee, maintaining federal compliance policies for research integrity; interacting with the Office of Research Integrity on behalf of the University around investigations; and supporting the DO in the Research Misconduct process.

### General Policies and Principles

#### 1.0 Policy

All institutional members will report observed, suspected or apparent research misconduct to the RIO. An institutional member may have confidential, informal, anonymous and/or hypothetical discussions about whether an activity meets the definition of research misconduct or about any concern regarding possible misconduct with the RIO at 651-690-8822 and will be counseled about appropriate procedures for reporting allegations.

1. Institutional members will cooperate with the RIO and institutional officials in review of allegations and conduct of inquiries and investigations.
2. Institutional members, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.
   a. Confidentiality - The RIO shall limit disclosure of the identity of respondents and complainants and except as otherwise prescribed by law, limit disclosure of records or evidence from which research subjects might be identified to those who need to know to carry out a research misconduct proceeding.
   b. The RIO should use written confidentiality agreements or other mechanisms to ensure a recipient does not disclose information.
3. Protection of the Complainant, Witnesses and Committee Members - Institutional members may not retaliate against complainants, witnesses, or committee members. During research misconduct proceedings and upon completion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO must undertake all 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. Any alleged or apparent retaliation against complainants, witnesses or committee members should be reported to the RIO.

4. Restoration of Respondent’s Reputation – Following a finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent’s reputation. Depending on particular circumstances and views of the respondent, the RIO should consider notifying individuals aware of or involved in the investigation of 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 institutional actions to restore the respondent’s reputation should first be approved by the DO.

5. During misconduct proceedings, the RIO is responsible for ensuring respondents receive all notices and opportunities provided for in this policy and copies of the University's policies and procedures. Respondents may seek advice from a personal advisor (not a principal or witness in the case) and bring the adviser to interviews or meetings.

6. Throughout the proceeding, RIO will determine if there is any threat of harm to public health, funds and equipment, or to the integrity of PHS-supported research process. If potential exists, in consultation with other institutional officials and ORI, ROI will take interim action to protect against such threat, such as through additional monitoring of research process, handling of federal funds and equipment, reassignment of personnel, suspension of research activities, additional review of research data/results or delaying of publication or if there is reasonable indication of violations of civil or criminal law, as federal action may be required.

7. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if:
   a. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
   b. HHS resources or interests are threatened;
   c. Research activities should be suspended;
   d. Reasonable indication of possible violations of civil or criminal law;
   e. Federal action is required to protect the interests of those involved in the research misconduct proceeding;
   f. Misconduct proceeding may be made public prematurely and HHS action is needed to safeguard evidence and protect rights of those involved.
   g. The research community or public should be informed.

8. The RIO must file a report and required compliance documentation annually with the ORI.

**Conducting the Assessment and Inquiry**

**1.0 Policy**

*Pre-Inquiry Assessment of Allegations* - Within a week of receiving a misconduct allegation, the RIO will interview complainant, respondent, or other witnesses to gather data to determine if all three of the following criteria are met—in which case a full inquiry must be conducted:

1. Allegations are sufficiently credible and specific so that potential evidence of research misconduct may be identified.
2. Allegations fall within the scope of the Research Misconduct policy.
3. Allegations fall within the definition of research misconduct as written in the policy.

The RIO will offer the respondent the opportunity to admit misconduct occurred during the interview and that he/she committed it. Based on an admission, the Deciding Official may terminate review of an allegation, if acceptance of the admission and any proposed settlement is approved by ORI.

Upon determining an inquiry must be conducted, the RIO will immediately initiate the inquiry process to conduct an initial review of available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all evidence related to the allegation.

2.0 Procedures for Full Inquiry

1. Notice to Respondent and Sequestration of Research Records - Before beginning an inquiry, the RIO must make a good faith effort to notify all respondents in writing, if known.
   a. Before the respondent is notified or the inquiry begins, whichever is earlier, the RIO must take reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the misconduct proceeding.
   b. Inventory records and evidence, and sequester them in a secure manner, except where the research records or evidence encompass scientific instruments shared by a number of users. In this case, 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.
   c. The RIO may consult with ORI for advice and assistance in this regard.

2. Appointment of the Inquiry Committee - After initiation of the inquiry, the RIO appoints the Inquiry Committee and Chair consisting of individuals without unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and with appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. The RIO will:
   a. Prepare a charge for the Inquiry Committee per policies and procedures.
   b. Convene a first meeting of the Inquiry Committee to brief the committee on the allegations, the charge to the committee and procedures to conduct an inquiry.
   c. Provide the Inquiry Committee with logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews.
   d. Be available throughout inquiry to advise the committee as needed prior to its decision on whether to recommend that an investigation is warranted.

3. First Meeting Tasks –
   a. Sets forth the time for completion of the inquiry.
   b. Describe allegations and related issues identified during the assessment.
   c. State purpose of inquiry is to conduct initial review of the evidence, including testimony of respondent, complainant and key witnesses; determine whether an investigation is warranted; but not to determine if misconduct definitely occurred or who was responsible.
   d. State that an investigation is warranted if Committee determines reasonable basis for concluding the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and the allegation may have substance based on the Committee's review during the inquiry.
   e. Inform Inquiry Committee they are responsible for preparing or directing the preparation of a written report of the inquiry that meets requirements of this policy and 42 CFR § 93.309(a).

4. Inquiry Process - Inquiry Committee will interview the complainant, respondent, and key
witnesses and examine relevant research records and materials and evaluate the evidence, including the testimony obtained during the inquiry.

a. After consultation with RIO, the Committee will decide whether an investigation is warranted based on criteria in this policy, definition of research misconduct and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

a. Scope of inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI to determine the next steps that should be taken. See Section IX.

4. Time for Completion - The inquiry, including preparation of the final report and decision of the DO on whether an investigation is warranted must be completed within 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period.

a. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

The Inquiry Report

1.0 Policy

1. A written inquiry report must be prepared that includes the following information:

a. Name and position of the respondent;

b. Description of the allegations of research misconduct;

c. PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support;

d. Basis for recommending or not recommending that the allegations warrant an investigation;

e. Comments on the draft report by the respondent or complainant names and titles of the Committee members and experts who conducted the inquiry; summary of the inquiry process used; a list of research records reviewed; summaries of interviews; and whether any other actions should be taken if an investigation is not recommended.

2. Institutional counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and Inquiry Committee.

3. 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 10 days, and include a copy of or refer to 42 CFR Part 93 and the institution’s policies and procedures on research misconduct.

2.0 Procedure

Confidentiality agreements are a condition to allow access to the inquiry report.

1. Any comments submitted by the respondent or complainant will be attached to the final inquiry report. Based on 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.

2. Institutional Decision and Notification - 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—which completes the Inquiry Process.

3. Notification to ORI - Within 30 calendar days of the decision an investigation is warranted, RIO
will notify appropriate institutional officials and provide ORI with the DO’s written decision and a copy of the inquiry report and attachments.

4. Upon ORI request, the ROI must provide:
   a. Institutional policies and procedures under which the inquiry was conducted;
   b. Research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents;
   c. Charges to be considered in the investigation.

5. Documentation of Decision Not to Investigate - If DO decides an investigation is not warranted, the RIO shall secure and maintain for sufficiently detailed documentation of the inquiry for 7 years after the termination of the inquiry to allow later assessment by ORI of reasons why an investigation was not conducted. Documents must be provided to ORI or other authorized HHS personnel upon request.

### Initiation and Purpose of Investigation

#### 1.0 Policy

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted. Purpose 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 determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond initial allegations. Findings of the investigation must be set forth in an investigation report.

#### 2.0 Procedure

1. Notifying ORI and Respondent; Sequestration of Research Records - On or before the date the investigation begins, RIO must:
   a. Notify ORI Director of the decision to begin the investigation and provide a copy of the inquiry report.
   b. Notify respondent in writing of allegations to be investigated within 30 days after the institution decides to begin an investigation, including any new allegations of misconduct not addressed in the inquiry or in the initial notice of investigation within a reasonable amount of time of deciding to pursue new allegations.

2. The RIO will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester all research records and evidence needed to conduct the misconduct proceedings that were not previously sequestered during the inquiry. Procedures to be followed for sequestration during the investigation also apply during the inquiry.

3. Appointment of Investigation Committee - RIO will appoint an Investigation Committee and Chair as soon after initiation as is practical, and prepare a charge for the Investigation Committee. The Investigation Committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the Investigation Committee may also have served on the Inquiry Committee. When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside the institution.

4. The Investigation Committee and RIO must:
   a. Ensure investigation is thorough and sufficiently documented and includes examination
of all research records and evidence relevant to reaching a decision on the merits of each allegation;
b. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
c. Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation;
d. Pursue all significant issues and leads that are determined relevant to the investigation, including evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

5. Time for Completion - The investigation is to be completed within 120 days, including conducting investigation, preparing the report, providing the draft report for comment and sending final report to ORI. If RIO determines the investigation will not be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay/extension. RIO will ensure periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

6. Convening the first meeting of Investigation Committee:
   a. Briefing committee on the charge, inquiry report and procedures and standards for conduct of investigation, including need for confidentiality and developing a specific plan for investigation;
   b. Providing committee members a copy of institution’s policies and procedures and 42 CFR Part 93.
   c. Providing the Investigation Committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence and clerical support including arranging interviews with witnesses and recording or transcribing those interviews.
   d. Being available throughout the investigation to advise the committee as needed.

RIO Ensures Investigation Committee -
1. Uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on merits of the allegations and that is otherwise thorough and sufficiently documented;
2. Takes reasonable steps to ensure an impartial and unbiased investigation to maximum extent practical;
3. Interviews each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by respondent, and records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the corrected recording or transcript in the record of the research misconduct proceeding.
4. Pursues diligently all significant issues and leads discovered that are relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continues the investigation to completion.
5. If the extension is granted, the RIO will file periodic progress reports with ORI.
   i. Assisting the Investigation Committee in preparing a draft investigation report that meets the requirements of 42 CFR Part 93 and the institution’s policies and procedures, sending the respondent (and complainant at the institution’s option) a copy of the draft report for his/her comment within 30 days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from respondent (and complainant at the institution’s option) and ensuring that the comments are included and considered in final investigation report.
ii. Transmitting draft investigation report to institutional counsel for review of legal sufficiency.

iii. Assisting the Investigation Committee in finalizing the draft investigation report and receiving the final report from the committee.

9. Transmitting the final investigation report to the DO.
The Investigation Report

1.0 Policy

The Investigation Committee and the RIO are responsible for preparing a written draft that:

1. Describes the nature of the allegation of research misconduct, including identification of the respondent, which may include the respondent’s CV.

2. Describes and documents PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support.

3. Describes the specific allegations of research misconduct considered in the investigation.

4. Includes institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously.

5. Identifies and summarizes the research records and evidence reviewed and identifies evidence taken into custody but not reviewed.

6. Includes a statement of findings for each allegation of research misconduct identified during the investigation that:
   a. Identifies whether misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly
   b. Summarizes the facts and 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
   c. Identifies the specific PHS support
   d. Identifies whether any publications needs correction or retraction
   e. Identifies person(s) responsible for the misconduct
   f. Lists any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.

2.0 Procedure

1. 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 draft and final report.

2. On a case-by-case basis, the institution may provide the complainant a copy of the draft investigation report or relevant portions of it for comment. The complainant’s comments must be submitted within 30 days of the date on which he/she received the draft report and the comments must be included and considered in the final report. See 42 CFR §§ 93.312(b) and 93.313(g).

3. Confidentiality - In distributing the draft report, or portions thereof, to the respondent and complainant, RIO will inform the recipient of the confidentiality under which the draft report is made available and require that recipients sign a confidentiality agreement.

4. Decision by Deciding Official - The RIO will assist the Investigation Committee in finalizing the draft investigation report, including ensuring that the respondent’s and complainant’s comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the Investigation Committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the Investigation Committee. Alternatively, the DO may return the report to the Investigation
Committee with a request for further fact-finding or analysis.

5. When a final decision on the case has been reached, the RIO will 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 notification requirements of sponsoring agencies.

6. Appeals - An appeal may be completed by the respondent requesting a reversal or modification of the institution’s finding of research misconduct within 120 days of filing the Investigation Report or unless ORI finds good cause for an extension based upon the institution’s written request. If ORI grants an extension, it may direct the filing of periodic progress reports.

7. Notice to ORI of Institutional Findings and Actions - Unless an extension has been granted, the RIO must, within the 120-day period of completing the investigation or related appeal, submit the following to ORI: (1) a copy of the final investigation report with all attachments or any related appeal; (2) a statement of whether the institution accepts the findings of the investigation report or outcome of an appeal; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.

   a. Maintaining Records for Review by ORI - The RIO must maintain and provide to ORI upon request “records of research misconduct proceedings”. 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. The RIO is responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation or of the institution’s handling of such an allegation.

### Completion of Cases; Reporting on Premature Closures to ORI

#### 1.0 Policy

All inquiries and investigations will be carried through to completion.

8. 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:

   a. Closing of a case at the inquiry stage on the basis that an investigation is not warranted.
   b. Finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.

### Institutional Administrative Actions (Optional)

#### 1.0 Policy

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

1. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found.
2. Removal of responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment.
3. Restitution of funds to the grantor agency as appropriate.
4. Other action appropriate to the research misconduct.
Other Considerations

1.0 Policy
The termination of the respondent’s institutional 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 the institution’s responsibilities under 42 CFR Part 93.

1. If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of allegation will proceed, as well as 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 RIO and any Inquiry or Investigation Committee will use their best efforts to reach a conclusion concerning allegations, noting in the report the respondent’s failure to cooperate and its effect on the evidence.

2. The DO will determine, after consulting with the RIO and the complainant, witnesses or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or counter potential or actual retaliation against them. RIO is responsible for implementing steps the DO approves.

3. Allegations Not Made in Good Faith - If relevant, the DO will determine whether the complainant’s allegations of misconduct were made in good faith or whether a witness or committee member acted in good faith. If the DO determines there was an absence of good faith, he/she will determine whether administrative action should be taken against the person who failed to act in good faith.