

80.20.006 RESEARCH MISCONDUCT POLICY

Research Misconduct Policy

Derived from St. Jude Policy 70.05.001 (Owner, Audrey Wilson)

PURPOSE

This policy replaces Section 300.1 of the St. Jude Faculty handbook.

- To protect scientific research integrity at St. Jude and to comply with federal regulatory requirements under 42 C.F.R. Part 93 regarding reporting and investigating allegations of Research Misconduct.
- This policy and accompanying Standard Operating Procedures supersede the St. Jude faculty handbook policy 300.1 entitled "Scientific Misconduct."

SCOPE

- This policy applies to all research activities conducted under the auspices of St. Jude and includes but is not limited to "Institutional Members." Entities with which St. Jude has consortium or contractual arrangements and who receive US Public Health Services ("PHS") support through St. Jude shall have an assurance on file with the Office of Research Integrity ("ORI"), and internal policies in compliance with 42 CFR 93 regarding procedures for investigating and reporting possible Research Misconduct to ORI.
- Conduct covered under this policy:
 - Research misconduct is defined by the ORI regulations as 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.
 - Fabrication is making up data or results, and recording or reporting them.
 - 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 is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit to the other person.
 - St. Jude has more stringent standards than the narrow definition of research misconduct defined in the federal regulations, and may find conduct to be actionable under its standards even if the action does not meet the federal definition of research misconduct.
 - Conduct that does not meet ORI's definition of Research Misconduct but warrants investigation and action by St. Jude under this policy includes:
 - intentional or reckless disregard for or significant and substantial departure from accepted research practices, applicable federal regulations, St. Jude policies, Institutional Review Board ("IRB") directives on the appropriate and ethical conduct of human subjects research, Institutional Animal Care and Use Committee ("IACUC") directives on the appropriate and ethical conduct of animal research, or recognized research ethics;
 - the falsification of academic or professional credentials; and
 - the submission to journals or research sponsors of work product that contains intentional or reckless material misstatements or omissions.
 - A finding of research misconduct occurs if there is a significant departure from accepted practices at St. Jude that were committed intentionally, knowingly or recklessly, and proven by preponderance of the evidence.
 - Authorship disputes are addressed in the St. Jude Faculty Handbook Section 200.12.1.
- Time Limitations

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- Research Misconduct occurring more than six years prior to submission of the allegation will not be investigated unless there is compelling reason to do so:
 - the alleged Research Misconduct was not reasonably discoverable at an earlier time;
 - the Respondent has continued or renewed conduct allegedly constituting Research Misconduct that occurred before the six-year limitation; or
 - the Research Misconduct poses a current threat to the health and safety of patients, animals, and/or employees.

STAKEHOLDERS AFFECTED BY THIS POLICY

Stakeholders who must comply with this policy include all St. Jude Children's Research Hospital Graduate School of Biomedical Sciences ("Graduate School") students and faculty members participating in research activities.

POLICY

1.1 The RIO at St. Jude is responsible for assessing Research Misconduct Allegations, determining when Allegations warrant Inquiries, recommending Investigations or administrative actions based on Inquiry conclusions, and overseeing Inquiries and Investigations. The Deciding Official appoints the RIO for St. Jude. The RIO works with Legal Services and Compliance to implement the institution's Research Misconduct policies and procedures.

PROCEDURE

2.1 The procedures and conditions of Research Misconduct proceedings are fully described in the Research Misconduct Standard Operating Procedure found on the Compliance and Human Resources intranet websites.

2.2 Reporting Misconduct Allegation

2.2.1 If an individual is unsure whether a suspected incident falls within the definition of Research Misconduct, he or she may confidentially and informally consult the RIO about the suspected misconduct. The RIO will accept any Allegation, discuss the circumstances with Legal Services, and respond to the individual.

2.2.2 An individual who is not comfortable bringing their concerns to the RIO may direct those concerns to any St. Jude Administrator, who is then required to forward the Allegation to the RIO.

2.2.3 Institutional Members shall report suspected Research Misconduct to a St. Jude Official. When a St. Jude Official receives an Allegation, he or she shall notify the RIO immediately. The RIO shall notify Legal Services, and Compliance if the Allegation requires investigation by or input from Compliance.

2.3 Research Misconduct Initial Review and Inquiry

2.3.1 A Respondent has a right to thorough, competent, objective, and fair response to Allegations of Misconduct.

2.3.2 Complainant, Respondent, and witness interviews shall take place in a private environment.

2.3.3 If after initial review of the alleged facts, or after the Inquiry, the RIO and Legal Services determine that circumstances described do not meet the definition of Research Misconduct, the RIO will refer the individual or concern to other St. Jude offices or officials with the responsibility for resolving the concern. If the concern involves a faculty member or student at the Graduate School, and the RIO and Legal Services determine that the circumstances described do not meet the definition of Research Misconduct but rather relate to an alternate issue relevant to the Graduate School, the RIO will refer the individual or concern to the Graduate School. If an Allegation is not made in good faith, the RIO and Legal Services will work with the Complainant's supervisor, HR, and other departments as appropriate to determine if disciplinary action should be implemented.

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2.3.4 If after initial review of the alleged facts, the RIO and Legal Services determine that the Allegation is sufficiently credible and specific and an Inquiry is warranted, the RIO shall notify the Respondent in writing immediately. If the Inquiry results in facts that require further scrutiny, the RIO will recommend to the Deciding Official that an Investigation should be conducted. If an Allegation involving a Graduate School student meets the definition of Research Misconduct, and the RIO suspects academic misconduct, the RIO and Legal Services will notify the Dean of the Graduate School. The Graduate School will initiate a review and investigation process for academic misconduct, as outlined in the Graduate School Student Professionalism Policy.

2.3.5 An Inquiry shall be completed within 55 calendar days of the initial Allegation unless circumstances warrant a longer period.

2.3.6 The RIO will take custody of the research records, review the evidence, and prepare and submit an Inquiry Report to the Respondent and Deciding Official. The Respondent will have five calendar days to review the report and submit a response to the RIO.

2.3.7 After reviewing the Inquiry Report and Response, the Deciding Official will determine within 30 calendar days of receiving the Report whether the evidence warrants an Investigation, even if the Complainant does not wish to pursue the Allegation. If there is an Inquiry that recommends an Investigation involving a faculty member or student at the Graduate School, the Dean of the Graduate School will be notified.

2.4 Ad hoc Committee of Investigation

2.4.1 The RIO and Deciding Official appoint the Committee. The Committee consists of senior St. Jude faculty members with appropriate scientific expertise, and who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Inquiry or Investigation (RIO, Complainant, Respondent, witnesses).

2.4.2 The Deciding Official appoints the Committee Chair, who is responsible for maintaining a detailed record of the Committee's actions.

2.4.3 During the Investigation, St. Jude will take action necessary to protect public health and safety, federal funds, the research integrity process, and reputations.

2.4.4 Upon conclusion of the Investigation, the Committee will write its findings in an Investigation Report, which is provided to the Respondent. The Respondent may write a rebuttal within 30 calendar days of receiving the Committee's Report for the Committee to consider. The Committee may modify its findings in an Addendum to the Report based on new facts provided in the Respondent's Response. The Committee may recommend administrative actions to the Deciding Official. The Report, Response, and Addendum, and recommended administrative actions are provided to the Deciding Official for final determination, and to ORI according to federal regulations.

2.5 Duty to Cooperate with Research Misconduct Proceedings

2.5.1 Institutional Members are required to participate in Research Misconduct proceedings and shall provide relevant evidence of the Allegations to the RIO and Legal Services. If an Institutional Member refuses to cooperate according to this policy and its related procedures, the Deciding Official may impose disciplinary actions, up to and including termination of employment from St. Jude.

2.6 Protection of the Complainant, Respondent, and Others

2.6.1 Disclosure of the identity of Respondents, Complainants, and records or evidence from which research subjects might be identified in Research Misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair Research Misconduct proceeding, and as

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allowed by law. Provided, however, that St. Jude must disclose the identity of Respondents and Complainants to ORI.

2.6.1.1 The rights and reputation of Respondents, Complainants, and research subjects identifiable from research records or evidence, and all other parties involved in Research Misconduct proceedings shall be protected throughout the proceedings, to the extent possible without compromising public health and safety.

2.6.1.2 Legal Services will work with the RIO and institutional leadership during an Inquiry and an Investigation to determine how best to share information and findings with necessary agencies and parties.

2.6.2 St. Jude prohibits retaliation for making an Allegation. In accordance with institutional policy 70.01.006 "Non-retaliation for Reporting Suspected Non-Compliance," no one shall suffer Retaliation for making an Allegation or for providing evidence or testimony during Research Misconduct Proceedings. The RIO and Legal Services will verify that an Allegation is made in good faith.

2.6.3 Respondent has a right to an Advisor. At Respondent's request and faculty's consent, a St. Jude faculty member in good standing and with no conflicts of interest in the matter may act as an advisor to a Respondent, and with notice to the RIO, may accompany the Respondent as an observer of interviews or meetings where the Respondent's presence is requested or required.

2.6.4 If at any time during a Research Misconduct Proceeding, information is obtained that reasonably indicates that criminal violations may have occurred, the RIO must notify Legal Services within 24 hours. Legal Services will assess alleged criminal or civil violations case-by-case to ascertain relevant facts and determine the best course(s) of action. If the violations are likely to have occurred, Legal Services and the RIO will notify ORI, and any other appropriate parties (such as a funding agency or law enforcement), as appropriate

2.6.5 Resolution of an Investigation by the Deciding Official may include a finding that administrative action is necessary and a retaliation prevention plan for Committee members, witnesses, and Complainant(s) is needed. If no Research Misconduct is found, a plan to restore the Respondent's reputation shall be developed.

2.7 Administrative and/or Disciplinary Actions for Findings of Research Misconduct

2.7.1 If the Deciding Official determines that the alleged Research Misconduct is substantiated, he or she will decide on the appropriate administrative or disciplinary actions to be taken with the Respondent, up to and including termination from employment at St. Jude. The RIO will notify and make reports of those actions, and any documentation needed to restore the scientific record, to ORI and other parties and agencies as required.

2.7.2 If the Deciding Official determines that an Allegation was not made in good faith, he or she will decide on the appropriate administrative or disciplinary actions to be taken with the Complainant, up to and including termination from employment at St. Jude.

2.8 Record Retention

2.8.1 Regardless of the outcome, after completion of a Research Misconduct Investigation and related actions, the RIO and Legal Services will prepare a complete file, including the records of the Inquiry and Investigation and copies of all transcripts, documents, and other materials furnished to the RIO or the Committee (the "Records"), and will transfer the Records to the Office of Legal Services for retention.

2.8.2 The Records shall be retained in a secure manner for seven years.

2.8.3 ORI and other authorized government personnel will be given access to the Records as required by law and in accordance with applicable St. Jude policies.

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DEFINITIONS

- **Ad Hoc Committee of Investigation** – Senior faculty members who the Deciding Official and the RIO appoint to examine and evaluate relevant facts and determine whether Research Misconduct has been committed and if so, by whom.
- **Allegation** – Any written or oral statement or other communication of possible Research Misconduct made to a St. Jude Official. The four phases of responding to an Allegation are initial assessment, Inquiry, Investigation, and resolution.
- **Complainant** – An individual who makes an Allegation of Research Misconduct.
- **Deciding Official** – An institutional member who makes final determinations on Research Misconduct proceedings and any responsive St. Jude actions. At St. Jude, the Deciding Official is the Chief Executive Officer.
- **Good Faith Allegation** – A claim of wrongdoing made with the honest belief that Research Misconduct may have occurred. An Allegation is not in good faith if it is groundless or made with knowing or reckless disregard for information that would negate the claim.
- **Inquiry** – Preliminary information-gathering and initial fact-finding by the RIO and Legal Services in compliance with 42 CFR 93.307-309 to determine whether an Allegation or apparent instance of Research Misconduct warrants an Investigation.
- **Institutional Member(s)** – A person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional Members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and sub awardees, and their employees.
- **Investigation** – Formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct, or to a recommendation for a finding of research misconduct, which may include a recommendation for other appropriate actions, including administrative actions.
- **ORI** – The Office of Research Integrity within the U.S. Department of Health and Human Services that oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of Health and Human Services and the American public.
- **Research** – A systematic experiment, study, evaluation, demonstration, or survey designed to determine the safety and effectiveness of medications, devices, diagnostic products, and treatment regimens intended for human use (clinical research), or to develop or contribute to general scientific knowledge (basic research) or specific scientific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating, or confirming information about, or the underlying mechanism relating to, biological causes, functions, or effects, diseases, treatments, or related matters to be studied.
- **Research Integrity Officer (“RIO”)** – The individual at St. Jude who is responsible for working with the Office of Legal Services (“Legal Services”) to assess Allegations, determine when Allegations warrant an Inquiry, and if there is sufficient evidence of potential Research Misconduct to warrant an Investigation. The RIO oversees Inquiries and Investigations. The Chief Executive Officer appoints the RIO for St. Jude.
- **Respondent** – The person(s) against whom an Allegation of Research Misconduct is directed or the person(s) whose actions are the subject of an Inquiry or Investigation.
- **Retaliation** – An adverse action taken against a Complainant, witness, or Committee member by St. Jude or one of its employees in response to a Good Faith Allegation of Research Misconduct, or good faith cooperation with a Research Misconduct proceeding.

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- **St. Jude Official** – An institutional member with the authority and responsibility to respond to and/or report Allegations of Research Misconduct. Such officials include the Chief Executive Officer, Research Integrity Officer, members of Legal Services, and Compliance Office (“Compliance”).

REFERENCE DOCUMENTS

- St. Jude Faculty Affairs Handbook - THIS POLICY REPLACES Section 300.1 OF THE FACULTY HANDBOOK.
- 42 CFR Part 93 Public Health Services Policies on Research Misconduct
- St. Jude Progressive Disciplinary Process
- Office of Legal Services intranet site
- Compliance Office intranet site
- Graduate School Non-Retaliation Policy

FORMS AND OTHER DOCUMENTS

N/A

POLICY DETAILS

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Policy Alternate	Stacey Schultz-Cherry
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