

**Children’s Hospital and Health System, Inc.
Administrative Policy and Procedure**

SUBJECT – Misconduct in Research Practices

POLICY

Children’s Research Institute recognizes the importance of ensuring the integrity of the research conducted within the organization and the duty each investigator has to protect the integrity of scientific endeavors. This statement of policy and procedures is intended to carry out Children’s Hospital and Health System’s (CHHS) responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93.

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I. APPLICABILITY AND DEFINITIONS

A. APPLICABILITY

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

- Any person who, at the time of the alleged research misconduct, was involved in any research proposed, conducted or reported by Children’s Research Institute (CRI), CHHS; or
- Any research proposed, conducted or reported elsewhere by any person as part of their CRI or CHHS employment or contractual duties; or
- Any research proposed, conducted or reported where CRI, CHHS, or Children’s Hospital of Wisconsin official affiliation is claimed, cited or implied in connection with such research.

This policy and procedure does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six

years of the date the institution or HHS received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b). This policy and procedure does not apply to allegations of questionable or unacceptable research practices, which will be reviewed under a separate inquiry and investigation process.

As federal funding agencies recognize, the primary responsibility for the conduct of research misconduct inquiries and investigations rests with the awarded institution. When allegations of misconduct involve investigators of a CRI affiliated institution, CRI will contact the appropriate officials at that institution and that institution may elect to initiate its own investigation as secondary to CHHS's or CRI's investigation.

B. DEFINITIONS

1. Research misconduct

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication means making up data or results, and recording or reporting them.
- Falsification means 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 means the appropriation of another person's ideas, processes, results or words without giving appropriate credit.

A finding of research misconduct requires that:

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

2. Inquiry

An inquiry is preliminary information-gathering and fact-finding to determine whether an allegation or an apparent instance of misconduct merits an investigation being conducted.

3. Investigation

An investigation is a formal development of a factual record and examination of relevant facts to determine whether or not misconduct has occurred.

II. RESPONSIBILITY TO REPORT MISCONDUCT

All institutional members should report observed, suspected, or apparent research misconduct to the Director of Corporate Compliance, who shall serve as the Research Integrity Officer (RIO) or his or her designee. Reporting such concerns will not jeopardize the employment of the individual who brought the complaint (the "complainant"). CHHS prohibits retaliation against a person who, acting in good faith, reports or provides information about suspected misconduct. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO may refer the individual or allegation to other individuals with responsibility for resolving the issues.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

III. REVIEW PROCESS AND TIME FRAME

A. PRELIMINARY ASSESSMENT

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

B. INQUIRY

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. An inquiry does not require a full review of all of the evidence related to the allegation.

1. At the time of, or before the beginning of an inquiry, the RIO will take all reasonable and practical steps to obtain custody of the research records and evidence needed to conduct the misconduct proceeding, inventory the records and evidence, and sequester them in an appropriate manner.
2. At the time of, or before the beginning of an inquiry, the RIO must make a good faith effort to notify the accused individual (the “respondent”) in writing, if the respondent is known. The respondent will be informed of the allegations, and allowed to comment on them. The respondent will also be given a copy of the draft report of the inquiry, and an opportunity to comment on the findings. Where appropriate, the respondent will be given copies of or granted supervised access to the relevant research records. The RIO will use reasonable efforts to protect the confidence of the complainant.
3. Relevant individuals, including the complainant, if possible, should be interviewed.
4. The final report, including a recommendation as to whether or not a full investigation is warranted, is to be submitted by the RIO to the General Counsel to review for legal sufficiency. The final report is to include the name and position of respondent, allegations of research misconduct, PHS support, information reviewed, any comments from the respondent, and the basis for conclusions reached. The final report should then be provided to the President of CHHS within 60 days of receipt of the allegation. If this time frame is not possible in any individual case, the RIO is to document the reasons and inform the President.
5. The documentation should include sufficient detail to permit a later assessment of the determination of whether or not a full investigation was warranted. It should describe the information reviewed, include a summary of the interviews conducted, state conclusions reached, and indicate whether or not the President believes an investigation is warranted.
6. The final report of the inquiry and a copy of the documentation will be provided to the President and must be maintained for seven years. The RIO will also notify the respondent of the outcome of the inquiry. A confidentiality agreement should be signed by the respondent as a condition to access to the report.

Unless the President has further concerns, the RIO’s recommendation that an investigation is not warranted will be final.

C. INVESTIGATION PROCEDURES

1. At the time of, or before the beginning of an investigation, the RIO take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.
2. The RIO will convene an investigation committee that will include a representative from legal services, the Vice President of Research Administration and, at the RIO's discretion, any other individuals with expertise related to the investigation.
3. The formal investigation should begin within 30 days of the completion of the inquiry and after written notice to the respondent. The investigation is to be completed and the final report sent to the President within 120 days from the date of notice of formal investigation.
4. An investigation should include examination of the relevant evidence and interviews of complainants, respondents, and witnesses. Complete written summaries of each interview should be provided to the individual being interviewed, and any comments should be included in the summary. The summaries will be retained by the President.
5. All significant issues should be pursued until the RIO is reasonably certain that he or she has gathered all available and appropriate information.
6. A draft written report of findings will be made available to the respondent with the opportunity to provide comments for the consideration of those conducting the investigation. A confidentiality agreement should be signed by the respondent as a condition to access to the report. Where identified, complainants should also receive the portions of the draft report regarding the statements they made during the investigation. Any comments on the draft from the respondent and from the complainants will be attached to the final report. If there is more than one respondent, and their involvements are not identical, separate draft reports should be prepared, if necessary to preserve confidentiality.
7. In addition to interview summaries and any comments by the respondent and complainant on the draft report, the final written report is to include:
 - a) a description of the policies and procedures followed;
 - b) the nature of the allegation of research misconduct, the identification of the respondent, and the PHS support involved;
 - c) a summary of research records and evidence reviewed and how relevant information was obtained;
 - d) a statement of findings for each allegation and basis for them;and

e) for each finding of research misconduct, a list of any publications that may need correction or retraction, and any current or pending support respondent has with any federal agencies.

IV. NOTIFICATION TO EXTERNAL AGENCIES

CHHS will comply with the applicable requirements and regulations of funding agencies.

- A. Under circumstances not involving federal funding agencies, the President will make the decision whether information about the allegations will be disclosed to the research sponsor. The President will consult with the General Counsel regarding such cases.
- B. In cases involving research funded by federal agencies, the RIO will notify the President and then the agency in the following situations:

- 1. **Outcome of an Inquiry**

- Federal funding agencies will be notified of the outcome of an inquiry involving funds from their agency only if that outcome includes the recommendation to conduct a full investigation.

- 2. **Commencement of an Investigation**

- Written notification will be provided to federal funding agencies upon determination that an investigation will be conducted. This notice is to be provided on or before the commencement of the investigation, and is to include all information required by the agency. Generally, this notice is to include at least the following: name(s) and position(s) of the respondent(s); general nature of the allegation(s); the agency support including any proposal or award numbers; the basis for the recommendation of an investigation; any comments by the respondent. This information will be held in confidence to the extent permitted by law.

- 3. **Written Request for a Time Extension**

- If the investigation and determination of discipline are likely to take more time than specified by the relevant funding agency's regulations to complete, the RIO will notify the federal funding agency, including reasons for the delay, interim progress reports, and the estimated date of completion of the report.

- 4. **Interim Reports**

- Federal funding agencies must be apprised during an investigation of facts that may affect current or potential funding of the individual

under investigation, or that may need to be disclosed in order to ensure proper use of federal funds or protection of the public interest.

5. Early Termination

Federal funding agencies must be notified of any decision to terminate an inquiry or investigation prior to the completion of all relevant requirements. This notice is to include the reasons for such action. Some agencies have retained the right to investigate the matter further on their own.

6. Final Outcome

Federal funding agencies must be notified of the final outcome of an investigation involving their funded project and provided with a complete copy of the final report.

7. Special Emergency Notifications

In addition, federal funding agencies will be informed at any stage of an inquiry or investigation if any of the following is discovered:

- an immediate health or safety hazard, including an immediate need to protect human or animal subjects
- an immediate need to protect federal, CRI or CHHS funds or equipment
- an immediate need to protect the integrity of the research or the research misconduct proceeding
- an immediate need to protect the interests of those involved in the research misconduct proceeding
- an immediate need to protect the interests of the research community or the public
- a likelihood that an alleged incident is going to be reported publicly
- a reasonable indication of possible criminal activity or civil law violation.

In special emergency circumstances as defined above, the RIO should inform the President, who will take any appropriate interim actions, if necessary, to protect public health, Federal funds, equipment and the integrity of the research process.

V. DETERMINATION OF DISCIPLINE

In cases where research misconduct is found, the President may take all appropriate actions she or he deems necessary to address the research misconduct. All such actions will be within the framework of any applicable CHHS Policies and Procedures.

VI. SAFEGUARDS

- A. In the course of conducting inquiries or investigations, the following safeguards will be applied:
1. Precautions will be taken to avoid unresolved personal, professional or financial conflicts of interest on the part of those involved in the inquiry or investigation.
 2. The identity of respondents, complainants, witnesses and research subjects will be protected throughout the research misconduct proceedings.
 3. Except as required in the reporting provisions above, only those directly involved in an inquiry or investigation or with a need to know will be made aware that the process is being conducted or have any access to records or evidence, including the identity of respondents, complainants, witnesses, and research subjects.
 4. Where appropriate, efforts will be made to protect and restore the reputations of the respondent(s) when allegations are not confirmed.
 5. Where appropriate, efforts will be made to protect and restore the reputations of a complainant or witness and to counter any retaliation against the complainant or witness.
 6. CHHS, CRI, all employees and agents will provide full and continuing cooperation with federal agencies during its oversight review of any ¹research misconduct investigations, hearings or appeals.

Approved by

Peggy Troy, President
Children's Hospital and Health System
(signed copy on file)

¹ Reference: 42 CFR Part 93