



Title	Research Misconduct Policy
Department/Division	CHRISTUS Institute for Innovation & Advanced Clinical Care/Clinical Excellence
Owner	System Director of Research
Approvers	Sam Bagchi, Pukar Ratti, Phyllis Everage, Francis Kanayo
Review Frequency	Every 3 years
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Last Review Date	May 2018

Purpose

The purpose of this policy is to define the behaviors that constitute research misconduct for investigators who perform research at a CHRISTUS Health facility and the outcomes, which may be taken depending on the misconduct that occurred.

Definitions

Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research.

Research Misconduct: Fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results as follows:

- 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.

Research Record: The record of data or results that embodies the facts resulting from scientific inquiry, including, for example, laboratory records, research proposals, reports, abstracts, thesis, oral presentations, journal articles, and any documents or materials provided by the subject of the allegations in the course of a research misconduct proceeding.

Policy

A thorough, competent, objective, and fair response to allegations of research misconduct consistent with and within the time limits of 42 C.F.R, part 93 will be performed, while ensuring a fair investigation to the extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with the following:

- Complainant
- Respondent, or
- Witnesses (42 C.F.R 93.304(b))

A. Investigators and other research personnel are expected to conduct research in accordance with the highest levels of ethical standards. Allegations of research misconduct defined above will undergo a preliminary inquiry to determine if a formal investigation is warranted.

B. Individuals may make an allegation of research misconduct orally or in writing, and must bring the allegation to the System Director of Research through the CHRISTUS Health Integrity line or Integrity link within the CHRISTUS Health Compliance department. The System Director of Research will determine whether the allegation is sufficient for investigation. If the System Director of Research determines that he/she has a conflict with determining the allegation veracity, he/she shall disclose the potential conflict to the System Chief Medical Officer, and a designated individual will be appointed to investigate the allegation.

Time Limits:

- All inquiries will be completed within 60 days of its initiation, unless circumstances clearly warrant a longer period. In this case, the inquiry records must include documentation of the reasons for exceeding the 60 day period (42 C.F.R 93.307(g))
- The Office of Human Subjects Research Protection Program (OHSRPP) at CHRISTUS Health will be provided with the written finding and a copy of the inquiry report within 30 days of finding that an investigation is warranted.
- All aspects of the investigations will be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comments in accordance with section 42 C.F.R 93.312, and sending the final report to Office of Research Integrity (ORI) under sections 42 C.F.R 93.315 and 42 C.F.R 93.311(a).
- Respondent will be notified in writing of the allegations within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins. Respondent will be given a written notice of any new allegations of research misconduct within a reasonable amount of time after deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation (42 C.F.R 93.310(c)).
- A written notice will be sent to the OHSRPP at CHRISTUS Health of any decision to open an investigation on or before the date on which the investigation begins (42 C.F.R 93.304(d)).

C. Allegations will be kept confidential to the extent possible and allowed by law. All efforts will be made to maintain high-levels of protection of confidentiality of the following:

- Respondents
- Complainants
- Research Subjects identifiable from research records or evidence.

D. The System Director of Research will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The System Director of Research, in conjunction with the Human Resources Department, will ensure that these individuals will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action. Individuals should immediately report any alleged or apparent retaliation.

E. If the allegation is deemed credible and specific, an Inquiry Committee will be called consisting of individuals from the site of alleged misconduct as well as from CHRISTUS Institute for Innovation & Advanced Clinical Care (CIIACC).

- The Respondent and Complainant will receive a copy of the preliminary Inquiry report and each will have 10 business days to comment.
- Based on the comments, the Research Integrity Officer (RIO) or Inquiry Committee at CHRISTUS Health may revise the Preliminary report, as appropriate. Typically, an IRB Administrator would serve the role of the RIO.
- Any comments made by the Respondent or Complainant will be included in the final Inquiry report.

F. A finding of research misconduct requires the following:

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

G. The inquiry records, including evidence, and paper-based records will be confidentially maintained in a secure manner for a period of 7 years after completion of the case. Compliance will provide access to paper-based records as required by law and in accordance with applicable Organization policies.

H. Resolution of an investigation may involve a finding that either the allegation(s) of misconduct cannot be substantiated or further action is necessary, such as disciplinary action, up to and including formal proceedings for dismissal. The nature of the disciplinary action taken will take into account the seriousness of the misconduct, including but not limited to:

- The degree to which the misconduct was known, intentional, or reckless;
- Whether the misconduct was an isolated event or part of a pattern; or
- If the misconduct had a significant impact on the research record, research subjects, other researchers, institutions, or the public welfare.

I. Allegations of research misconduct that involve federally funded research (or an application for federal funding) will be subject to notification of the appropriate federal agencies and CHRISTUS Health departments.

- If an Investigation is warranted for research that is federally funded (or proposed for federal funding), the RIO at CHRISTUS Health shall notify the Office of Research Integrity (ORI).
- The notification to the ORI shall be in writing within 30 days of finding that an Investigation is warranted and before the Investigation's start date.
- A copy of the final Inquiry report shall be included in the notification to the ORI. The report must contain:
 - Name and position of the Respondent(s);
 - General nature or description of the Allegation;
 - Public Health Service (PHS) application or grant numbers implicated by the Investigation
 - The basis for recommending an Investigation

J. Notification to the appropriate government agency (or agencies) within the agency's required time frames can occur upon ascertainment that any of the following conditions exist:

- There is an immediate public safety or health risk involved, including an immediate need to protect human subjects;
- There is an immediate need to protect federal funds or equipment;
- There is a need to suspend research activities;
- There is a need for federal action to protect the interests of those involved in the research misconduct proceeding;
- It is probable that the alleged incident is going to be reported prematurely to the public, so that appropriate steps are needed to safeguard evidence and protect the rights of those involved;
- The research community or public should be informed; or
- There is a reasonable indication of possible violations of civil or criminal law.

Written Notice to the respondent(s), consistent with and within the time limits of this part (42 C.F.R. 93.304(c))

- After receiving the Respondent and/or Complainant's comments to the preliminary report, if any, the Investigation Committee at CHRISTUS Health shall prepare a final Investigation report.
- The final report shall explain the specific Allegations of Research Misconduct, list and adequately substantiate its findings, describe the policies and procedures used to conduct the Investigation, describe how and from whom information/evidence was obtained, recommend corrections to the scientific record or other remedial action, if any, and include comments from the Respondent or Complainant.

All reasonable and practical efforts, if requested and as appropriate, will be made to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no findings of research misconduct is made (42 C.F.R, 93.3.4(k))

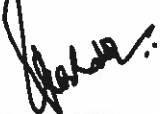
- If no Research Misconduct occurred and the Inquiry or Investigation damaged the Respondent's reputation, the RIO and System Director of Research, in conjunction with the Human Resources department at CHRISTUS Health shall discuss with the Respondent how to restore his or her reputation.

All reasonable and practical efforts will be made to protect or restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against these complainants, witnesses, or committee members (42 C.F.R, 93.3.4(l))

- Upon completion of an Investigation, if the Complainant's reputation has been damaged, the System Director of Research and the RIO at CHRISTUS Health will discuss with the Complainant how to restore his/her reputation.
- Such efforts would include, but not be limited to, affirmation that the allegations will have no adverse influence on future promotions, salary increases, access to institutional resources, and access to all other benefits appropriate for the individual's professional position. Such efforts and protection will also be extended to the Complainant if it is determined that the initial charge of research misconduct was made on the basis of faulty information or honest error in judgment, but not if the charge was found to be motivated by malicious intent.
- The System Director of Research at CHRISTUS Health must approve any institutional actions to restore the Respondent's or Complainant's reputation.

K. The relevant federal agency has the right under federal regulations to impose additional sanctions, beyond those applied by the institution, upon investigators or institutions, if it deems such action appropriate in situations involving funding from the agency.

Approved By:



Pukar Ratti, MSChE, MSHCM, CIM, CCRP, FACMPE
System Director of Research, & Institutional Official

15 MAY 2018
Date



Sam Bagchi, MD
SVP, System CMO, & System CMIO

05/24/18

Date