TITLE: Scientific Misconduct in Research		POLICY/PROCEDURE NUMBER: IRB 3	
Author:	Jana L. Lacera, RN, MSA, CDM	Applicable To:	CHS CIRB
Supersedes:	Scientific Misconduct/Unexpected Toxicity Related to Research	Issued By:	CFNI/CHS CIRB
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X	CFNI Munster, Indiana	X	Community Hospital Munster, Indiana	X	St. Catherine Hospital East Chicago, Indiana	X	St. Mary Medical Center Hobart, Indiana

POLICY/PROCEDURE STATEMENT/PURPOSE:

The purpose of these policies and procedures is to provide advice and guidance to Community Healthcare System (CHS) officials on the methods and principles for assessing Allegations of Research Misconduct, conducting Inquiries and Investigations related to possible Research Misconduct and reporting the results to Cognizant Federal Sponsors if an occurrence of Research Misconduct has been determined.

The procedures for handling Allegations of Research Misconduct, as defined in this policy, are mandated by federal regulations.

This policy applies to all individuals within the Community Healthcare System engaged in research, including any person paid by, under the control of, or affiliated with the Community Healthcare System, including, but not limited to scientists, trainees, technicians, employees and other staff members or individuals conducting research who are independent contractors under contract with CHS or who have staff privileges at any CHS entity.

The policy and associated procedures will be followed each time a Community Healthcare System official receives an Allegation of possible Research Misconduct.

It is the responsibility of all Staff, as defined in this policy, to report suspected Research Misconduct. These policies are provided to scientific and administrative staff, as well as all other persons subject to this policy, who are involved in the conduct of research in the Community Healthcare System.

The Community Healthcare Officials will take interim administrative actions in response to an allegation of Research Misconduct, as appropriate, to protect patient safety and Federal funds, and to ensure that the purposes of any applicable Federal financial assistance are carried out.

DEFINITIONS:

Allegation-means any written or oral statement or other indication of possible Research Misconduct made to a CHS official.

CHS CIRB- means the Community Hospital System Central Institutional Review Board.

Cognizant Federal Sponsor-means the federal sponsoring agency of the research project, including without limitation, the Public Health Service (PHS), National Institutes for Health (NIH), National Science Foundation (NSF), and the Food & Drug Administration (FDA), also referred to in the policy as the Federal Sponsor.

Conflict of Interest-means the real or apparent interference of any person's interests with the interests of another person or entity, including without limitation instances in which potential bias may occur due to prior or existing personal, professional or economic relationships.

Deciding Official-means the Chair of the CHS CIRB, who makes final determinations of Allegations of Research Misconduct and any actions taken to address the misconduct. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the Allegation assessment, Inquiry, or Investigation. If an actual or perceived conflict precludes the Chair of the CHS CIRB from serving in the capacity of the Deciding Official, the CHS official serving in the capacity as the Signatory Official for the purposes of the Federalwide Assurance will be the Deciding Official.

Director, ORI-means the Director of the Office of Research Integrity, the office within the Department of Health and Human Services (HHS) that is responsible for the Research Misconduct and research integrity activities of the Public Health Service.

Good faith allegation-means an Allegation made with the honest belief that Research Misconduct may have occurred.

Human Protections Administrator –means is the administrative coordinator of the CHS CIRB review process, serves as the OHRP primary contact for issues related to CHS CIRB review, and communicates CHS CIRB policies and procedures to Board Members, Investigators and their staff. Assures that administrative policies and procedures related to the ethical review of human subjects research in the Community Healthcare System are consistently carried out. Assures compliance with Federal regulations and state laws.

Inquiry-means information gathering and initial fact finding to determine whether an Allegation or apparent instance of Research Misconduct warrants an Investigation.

Institutional Legal Counsel-means one or more CHS legal counsel who is responsible for advising the Research Integrity Officer, the Inquiry and Investigation committee and the Deciding Official on relevant legal issues. The Institutional Counsel does not represent the Respondent, the Reporter, or any other person participating during the Inquiry, Investigation, or any follow-up action, except the CHS officials responsible for managing or conducting the CHS Research Misconduct process as part of their official duties.

Investigation-means the formal examination and evaluation of all relevant facts to determine if Research Misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

Investigation Committee- means the group of persons appointed by the Research Integrity Officer to conduct an Investigation into Allegations of Research Misconduct. The Research Integrity Officer will ensure that the Investigation Committee is comprised of individuals with sufficient technical expertise to conduct a full and complete Investigation into an Allegation of Research Misconduct.

ORI-means the Office of Research Integrity, the office within the Department of Health and Human Services (HHS) that is responsible for the scientific misconduct and research integrity activities of the Public Health Service.

PHS-means the Public Health Service, an operating component of the Department of Health and Human Services.

PHS Regulation-means the PHS regulations establishing standards for Inquiries and Investigations into Allegations of Research Misconduct which is set forth at 42 CFR Part 50, Subpart A, Responsibility *of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science.*

Reporter- means a person who makes an Allegation of Research Misconduct.

Research-means all basic, applied and demonstration research in all fields of sciences, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

Research Integrity Officer-means the Vice President Corporate Compliance, who is responsible for assessing Allegations of Research Misconduct and determining when such Allegations warrant Inquiries and for overseeing any Inquiries and Investigation.

Research Misconduct-means Fabrication, Falsification, Plagiarism or other misconduct in proposing or performing research or in reporting research results. It does not include honest error or differences of opinion. Research Misconduct includes other improper Research activities such as inappropriate treatment of living subjects, non-compliance with Institutional Review Board (IRB) policies or directives, fiscal malfeasance regarding Research and other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting Research.

1. Fabrication-making up data or results and recording or reporting them.

2. Falsification- is manipulating research materials, equipments, or processes, or changing or omitting data or results such that the Research is not accurately represented in the Research Record.

3. Plagiarism-is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research Record-means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported Research that constitutes the subject of an allegation of Research Misconduct. A Research Record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; x-ray film; slides; biological materials; computer files and printouts; manuscripts and publication; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; drug study accountability logs; case report forms and patient research files.

Respondent-means 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-means any action taken by the CHS or an individual that adversely affects the employment or other institutional status of an individual, who acting in good faith, has made an Allegation of Research Misconduct or who has cooperated in good faith with an Investigation of alleged Research Misconduct or of inadequate institutional response.

Staff-means any person paid by, under the control of, or affiliated with the Community Healthcare System, including, but not limited to scientists, trainees, technicians, employees and other staff members or individuals conducting research who are independent contractors under contract with CHS or who have staff privileges at any CHS entity.

GENERAL PROCEDURES AND PRINCIPLES

Responsibility to Report Research Misconduct
Staff who become aware of Research Misconduct or receive or learn of an Allegation of Research Misconduct will immediately report the Allegation to the Research Integrity Officer for appropriate action. The Research Integrity Officer will promptly engage in an assessment of the Allegation to determine whether it falls within the definition of Research Misconduct, involves PHS support, and provides sufficient information to proceed with an Inquiry.

Protecting the Reporter
Staff who receive or learn of an Allegation of Research Misconduct will treat the Reporter with fairness and respect and, when the Allegation has been made in good faith, will take reasonable steps to protect the position and reputation of the Reporter and other individuals who cooperate with CHS against retaliation. Staff will immediately report any alleged or apparent retaliation to the Research Integrity Officer.

Protecting the Respondent
Staff who receive or learn of an Allegation of Research Misconduct will treat the respondent with fairness and respect and will take reasonable steps to ensure that the procedural safeguards in the PHS regulation, 42 CFR Part 50, Subpart A, and these procedures are followed. Staff will report significant deviations from these instructions to the Research Integrity Officer. The Research Integrity Officer will report any Allegation not made in good faith to the Deciding Official for appropriate action.

Confidentiality
Staff who make, receive, or learn of an Allegation of Research Misconduct will protect, to the maximum extent possible, the confidentiality of information regarding the Reporter, the respondent, and other affected individuals. The Research Integrity Officer may establish reasonable conditions to ensure the confidentiality of such information.

General Policy for Responding to Allegations
In responding to Allegations of Research Misconduct, the Research Integrity Officer and any other CHS official with an assigned responsibility for handling such allegations will make diligent efforts to ensure that the following functions are performed.

1. Any Allegation assessment, Inquiry, or Investigation is conducted in a timely, objective, thorough, and competent manner.
2. Reasonable precautions are taken to avoid bias and real or apparent Conflicts of Interest on the part of those involved in conducting the Inquiry or Investigation.
3. Immediate notification is provided to ORI if:
    a. there is an immediate health hazard involved;
    b. there is an immediate need to protect Federal funds or equipment;
    c. 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 his/her co-investigators and associates, if any;
    d. it is probable that the alleged incident is going to be reported publicly;
    e. the Allegation involves a public health sensitive issue, *e.g., a* clinical trial;
    f. there is a reasonable indication of a possible Federal criminal violation. In this instance, the Research Integrity Officer must inform ORI within 24 hours of obtaining that information.
4. The Research Integrity Officer will, after consultation with Institutional Legal Counsel, notify any other sponsor of research activities involved in an Allegation of Research

Misconduct of the details of an Inquiry or Investigation as required by the terms of the agreement between the sponsor and the applicable CHS entity.

5. Interim administrative actions are taken, as appropriate, to protect Federal funds and the public health, and to ensure that the purposes of the Federal financial assistance are carried out.
6. The safety of each patient enrolled in any research study that is involved in an Allegation of Research Misconduct is protected.

This general policy for responding to Allegations of Research Misconduct will be followed in conjunction with the procedures for responding to Allegations described in herein. In the event of a perceived conflict between this policy and the specific procedures described herein, the procedures will control.

Staff Cooperation

Staff will cooperate with the Research Integrity Officer and other CHS officials in the review of Allegations and the conduct of Inquiries and Investigations. Staff have an obligation to provide relevant evidence to the Research Integrity Officer or other CHS officials on misconduct Allegations. Further, staff will cooperate with ORI, if applicable, in its conduct of Inquiries and Investigations, its oversight of CHS Inquiries and Investigations, and any follow up actions.

Evidentiary Standards

The following evidentiary standards apply to findings of Research Misconduct made under the PHS regulation.

Burden of Proof

The burden of proof for making a finding of Research Misconduct is on CHS.

Standard of Proof

Any finding of Research Misconduct will be established by a preponderance of the evidence. This means that the evidence shows that it is more likely than not that the respondent committed Research Misconduct.

Completion of Process

The Research Integrity Officer is responsible for ensuring that the Inquiry/Investigation process and all other steps required by this instruction and the PHS regulation are completed even in those cases where the respondent leaves CHS after Allegations are made.

Early Termination

If CHS plans to terminate an Inquiry or Investigation involving Federally funded research activities prior to completion of all the steps required by the PHS regulation, the Research Integrity Officer will notify ORI of the planned termination and the reasons therefore. ORI will review the information provided and advise the institution whether further investigation should be undertaken.

Requirements for Reporting to ORI or Other Federal or Commercial Sponsors of Research Activities

1. An institution's decision to initiate an Investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins when the Allegation under Investigation involves Federally funded research. At a minimum, the notification should include the name of the person(s) against whom the Allegations have been made, the general nature of the allegation as it relates to the PHS definition of Research Misconduct, and the PHS applications or grant number(s) involved. ORI must also be notified of the final outcome of the Investigation and must be provided with a copy of the Investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

2. If an institution plans to terminate an Inquiry or Investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer

will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

3. If the institution determines that it will not be able to complete the Investigation in 120 days, the Research Integrity Officer will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.

4. When PHS funding or applications for funding are involved and an admission of Research Misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of Research Misconduct as a basis for closing a case or not undertaking an Investigation without prior approval from ORI.

5. The Research Integrity Officer will notify ORI at any stage of the Inquiry or Investigation if:
   a. there is an immediate health hazard involved;
   b. there is an immediate need to protect Federal 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 his/her co-investigators and associates, if any;
   c. it is probable that the alleged incident is going to be reported publicly; or
   d. the allegation involves a public health sensitive issue, *e.g., a* clinical trial; or
   e. there is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.

6. The Research Integrity Officer will, after consultation with Institutional Legal Counsel, notify any non-Federal sponsor of research activities involved in an Allegation of Research Misconduct of the details of an Inquiry or Investigation as required by the terms of the agreement between the sponsor and the applicable CHS entity.

7. Potential violation of criminal law, including violations of the regulations promulgated by the Department of Health and Human Services (HHS) or under HHS grants and contracts should be referred to the Office of Inspector General (OIG), HHS-OIG Hot line, P.O. Box 17303, Baltimore, MD 21203-7303, telephone (800) 368-5779. If the possible criminal violation is identical to the alleged Research Misconduct *(e.g.,* alleged false statements in a PHS grant application), the criminal charge should be reported to ORI. ORI will then refer it to OIG.

8. Potential violations of human subject regulations should be referred to the Office of Human Research Protections, Department of Health and Human Services, 6100 Executive Boulevard, Suite 3B01, Rockville, MD 20892-7507. Phone: 301-496-7005. Email: ohrp@osophs.dhhs.gov.

9. Potential violations of animal subject regulations should be referred to the Office of Laboratory Animal Welfare, National Institutes of Health, 6705 Rockledge Drive, RKL1, Suite 1050, MSC 7982, Bethesda, MD 20892-7982, Phone: 301-402-5913.

10. Potential violations of Food and Drug Administration regulated research requirements should be referred to the FDA Office of Regulatory Affairs, Division of Compliance Policy, Bioresearch Program Coordination, 5600 Fishers Lane, HFC-230 TWBK 715, Rockville, MD 20857, telephone (301) 827-0420.

11. Potential violations of cost principles or other fiscal irregularities, including but not limited to misuse of research funds, test articles or equipment, should be referred as follows:
    a. For all NIH Agencies—Office of Management Assessment, NIH, Building 31, Room 1B05, Bethesda, MD 20892, telephone (301) 496-1361.
    b. For all other PHS Agencies—PHS Office of Grants and Contracts, 5600 Fishers Lane, Room 17A39, Rockville, MD 20857, telephone (301)443-6630.

12. If there are any questions regarding the proper referral research misconduct issues, the Research Integrity Officer may call the ORI Division of Research Investigations at (301) 443-5330 to obtain advice.

Time Limits

There are specific time limits imposed upon the steps described in completing an Investigation of Allegations of Research Misconduct. CHS shall:

1. Notify the Federal Sponsor of reasonable indications of criminal violations within 24 hours.
2. Produce an Inquiry report within 60 days of initiation of Inquiry unless a delay is clearly warranted.
3. Initiate an Investigation within 30 days of completion of an Inquiry if an Investigation is indicated.
4. Submit an Investigation report to the federal sponsor within 120 days of initiation of the Investigation.

Incorporation by Reference

This document incorporates by reference the policies promulgated by the Office of Research Integrity of the United States Department of Health and Human Services in its document, Model Policies for Responding to Allegations of Scientific Misconduct, available at http://www.ori.hhs.gov/documents/model_policy_responding_allegations.pdf. The optional provisions contained in that document have not been adopted unless specifically incorporated herein. Should a discrepancy exist between the Model Policies and the provisions of this document, the provisions of this document control. A copy of the Model Policies for Responding to Allegations of Scientific Misconduct is on file in the CHS Office of Human Research Protections and is available for review upon request.

PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

Inquiry of Allegations

1. Upon receiving an Allegation of Research Misconduct, the Research Integrity Officer will immediately assess the Allegation to determine:
    a. whether there is sufficient evidence to warrant an Inquiry,
    b. whether federal support or federal applications for funding are involved,
    c. whether the Allegation falls under the definition Research Misconduct, and
    d. whether there is sufficient cause to call an Investigation Committee to further investigate the Allegations.
    e. In case of doubt, the Research Integrity Officer should consult with the Institutional Legal Counsel on whether the Allegation falls within the definition of Research Misconduct.

2. All interviews, conversations, and other contacts made and actions taken in response to an Allegation of Research Misconduct will be documented and made part of the Inquiry record.

3. In the case of a vague Allegation, an effort should be made to obtain more information before initiation of an Inquiry. This information may be sought from any reasonable source, including the Reporter, if known.

4. After consultation with Institutional Legal Counsel, the Research Integrity Officer will notify the sponsor of research activities involved in an Allegation of Research Misconduct of any reasonable indications of criminal violations with 24 hours of finding.

5. The Research Integrity Officer will notify any applicable Federal Sponsor at any stage of this process if:
   a. there is an immediate health hazard involved;
   b. there is an immediate need to protect Federal funds or equipment;
   c. 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 his/her co-investigators and associates, if any;
   d. it is probable that the alleged incident is going to be reported publicly;
   e. the allegation involves a public health sensitive issue, e.g., a clinical trial;
   f. the allegation involves a risk to patient safety.

6. The Research Integrity Officer will, after consultation with Institutional Legal Counsel, notify any other sponsor of research activities involved in an Allegation of Research Misconduct of the details of an Inquiry or Investigation as required by the terms of the agreement between the sponsor and the applicable CHS entity.

7. The Research Integrity Officer has the responsibility to ensure that all Inquiries and/or Investigations will be conducted in such a manner that will protect the confidentiality of the proceedings and the rights and reputations of those individuals providing information to the extent possible.

8. The Research Integrity Officer will produce an Inquiry report within 60 days of initiation of the Inquiry unless a delay is clearly warranted. The Inquiry report shall contain sufficient details to permit a later assessment of the reasons for determining that an investigation was not warranted, if necessary. If the Inquiry report is not completed within the 60 day time period, the report will include a statement of the reasons for the delay in its completion.

9. The Respondent must be given a copy of the Inquiry report and will have a period of five (5) business days to submit written comments. Timely written comments by the Respondent will be incorporated into the record.

10. The Inquiry report will be maintained in a secure manner for a period of at least three years after the termination of the Inquiry, and shall, upon request, be provided to authorized HHS personnel.

<u>Initiation of an Investigation</u>

1. The Research Integrity Officer will initiate an Investigation within 30 days following the completion of the Inquiry if there has been a determination that Research Misconduct has potentially occurred.

2. When the Allegation of Research Misconduct involves Federally funded research, the Research Integrity Officer will report in writing to the Director, ORI, on or before the date the Investigation begins of the institution's decision to initiate an Investigation. The report to ORI shall include, at minimum:
   a. The name of the person(s) against whom the Allegation was made
   b. The general nature of the Allegation
   c. The PHS application or grant numbers involved

   The Research Integrity Officer similar report will be made to any other applicable sponsor of research activities involved in an Allegation of Research Misconduct as required by the

terms of the agreement between the sponsor and the CHS entity, after consultation with Institutional Legal Counsel.

3. The Research Integrity Officer, the Chair of the CHS CIRB and the Human Protections Administrator will appoint an Investigation Committee and ensure that the necessary and appropriate expertise is secured to carry out a thorough evaluation of the relevant evidence in an Investigation proceeding. Reasonable precautions will be taken to avoid bias and real or apparent Conflicts of Interest on the part of those involved in the conduct the Investigation.

4. All interviews, conversations, and other contacts made and actions taken in response to an Allegation of Research Misconduct will be documented and made part of the Investigation record.

5. The Respondent will be informed in writing within 7 days of receiving the Allegations that an Investigation has been opened.

6. The Research Integrity Officer will assist the Investigation Committee in interviewing the Reporter of the Allegation and any other individuals deemed necessary to gather the facts of the Allegation.

7. The investigation shall include examination of all relevant documentation including, without limitation, research data and proposals, publications, correspondence, and memoranda of telephone calls.

8. Whenever possible, interviews should be conducted of all of the individuals involved either in making the Allegation or against whom the Allegation is made, as well as other individuals who might have information about key aspects of the Allegations. Complete summaries of those Allegations should be prepared, provided to the interviewed party for comment, and included as part of the investigatory file.

9. The Investigation Committee will prepare and maintain documentation sufficient to substantiate the Investigation's findings. This documentation will be made available to ORI, if applicable, along with the Investigation report.

10. CHS will take interim administrative actions, as appropriate, to protect patient safety and Federal funds, and to ensure that the purposes of the Federal or commercial financial assistance of sponsored research activities are carried out.

11. If the Allegation of Research Misconduct involves Federally funded research or a recipient of Federal research funds, the Research Integrity Officer will keep the ORI apprised of any developments during the course of the Investigation which disclose facts that may affect current or potential HHS funding for the individual(s) under Investigation or that the PHS needs to know to ensure the appropriate use of Federal funds and otherwise protect the public interest.

12. The Reporter will have the opportunity to report to the Committee, to review portions of the reports pertinent to his/her Allegations or testimony, and to be informed of the results of the Investigation.

13. The final Investigation Report will describe the policies and procedures under which the Investigation was conducted, how and from whom information was obtained, the findings, and the basis for the findings, and shall include the actual text or an accurate summary of the views of any individuals found to have engaged in misconduct, as well as a description of any sanctions taken by CHS.

14. The Respondent will have the opportunity to be interviewed by and present evidence to the Committee, to review the draft Inquiry and Investigation reports, and to have the advice of legal counsel.

CHS Review and Decision

1. An Investigation should ordinarily be completed within 120 days of its initiation, with the initiation being defined as the first meeting of the Investigation committee. This includes conducting the Investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Deciding Official for approval, and submitting the report to the ORI, if applicable. If Federally funded research is involved and CHS determines that it will not be able to complete the investigation in 120 days, it shall submit to the ORI a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate of the date of the completion of the report and other necessary steps. If the extension is granted, CHS will submit periodic progress reports as requested by ORI.

2. Based on a preponderance of the evidence, the Deciding Official, in collaboration with the Research Integrity Officer, will make the final determination of whether to accept the Investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the Investigation Committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the Investigation Committee. The Deciding Official's explanation should be consistent with the definition of Research Misconduct, the policies and procedures established by the CHS CIRB, and the evidence reviewed and analyzed by the Investigation Committee. The Deciding Official may also return the report to the Investigation Committee with a request for further fact finding or analysis.

3. The Deciding Official may consult with the Institutional Counsel at any time during this process.

4. After comments have been received and the necessary changes have been made to the draft report, the Investigation Committee shall transmit the final report with attachments, including the Respondent's and Reporter's comments, to the Deciding Official and the Research Integrity Officer.

5. If the Deciding Official determines that the Allegation of Research Misconduct is substantiated by the findings, he/she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Officer. Disciplinary or remedial actions may be imposed directly by the Deciding Official. The actions or recommendations may include:
   a. withdrawal or correction of all pending or published abstracts and papers emanating from the research in which Research Misconduct was found;
   b. removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, suspension or termination of the particular project;
   c. Other disciplinary actions consistent with the employment and staff privileges policies of the CHS entity.

6. When a final decision has been reached, the Research Integrity Officer will notify both the Respondent and the Reporter in writing. In addition, the Deciding Official will determine whether law enforcement agencies, professional societies, professional licensing boards, collaborator of the Respondent in the study, or other relevant parties should be notified of the outcome of the case. The Research Integrity Officer is responsible for ensuring

compliance with all notification requirements of funding or sponsoring agencies and sponsor.

7. If federally funded research is involved, ORI must be notified of the final outcome of the Investigation and must be provided with a copy of the Investigation report. The Research Integrity Officer will, after consultation with Institutional Legal Counsel, notify any other sponsor of research activities involved in an Allegation of Research Misconduct of the details of an Inquiry or Investigation as required by the terms of the agreement between the sponsor and the applicable CHS entity

8. If the institution finds no misconduct and ORI concurs, if applicable, after consulting with the respondent, the Research Integrity Officer will undertake diligent efforts, as appropriate, to restore the respondent's reputation while protecting the positions and reputations of those who, in good faith, make Allegations. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

9. All documentation of the proceedings will be maintained by the Research Integrity Officer. All Inquiry and Investigation reports will be sufficiently documented and records maintained for a period of at least three (3) years. Upon request, these documents will be provided to HHS personnel.

Appeals

1. The decision of the Deciding Official regarding the final determination of Research Misconduct and the action taken shall be binding on the CHS CIRB and the Respondent(s) found to have engaged in Research Misconduct.

2. The Respondent(s) may appeal the decision to the Senior Vice President of Operations and the Board of Directors within 30 days of receiving notification. The decision of the Senior Vice President of Operations and the Board of Directors shall be final.

CROSS REFERENCE:
U.S. Public Health Service: 42 CFR Part 50, Subpart A, Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science

Office of Research Integrity (ORI), United States Department of Health and Human Services, Model Policy for Responding to Allegations of Scientific Misconduct.

Office of Research Integrity (ORI), United States Department of Health and Human Services, Model Procedures for Responding to Allegations of Scientific Misconduct.

ACCEPTED BY:

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DATE REVISED: 11/2017

REVIEWED BY: CHS CIRB January 2005, 6/2009, 4/2013, 3/2016, 2/2020, 2/2023
Institutional Legal Counsel Review February 2005
CFNI Board of Directors 7/20/05
MRF Board of Directors 8/23/05

Date	Initials
6/2009	JL
3/2013	JL
2/2016	JL
11/2017	JL
2/2020	JL
2/2023	KW