



Policy RES101

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| Subject | Responding to Allegations of Research Misconduct |
| Category / Section | Research |
| Owner | Human Protection Administrator |
| Stakeholder/ Reviewer(s) | Research Committee; Compliance |
| Approver(s) | Executive VP/CAO; Senior VP President/CMO; President/CEO |
| Review Frequency | Annual |
| Effective Date | 09/05 |
| Review Date | |
| Revision Date | 02/10 |

Scope of Policy (Identifies the entities that are covered under the policy)

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| | All Carle Locations | | Caring Place, The | | SurgiCenter, LLC - Champaign |
| | Carle Hospital | | Health Alliance | | SurgiCenter - Danville |
| X | Carle Physician Group | | Home Care | | SurgiCenter Recovery Centers |
| | Carle Foundation Physician Services | | Home Infusion | | Therapy Services |
| | AirLife | | Hospice | | Therapy Services - MTCH |
| | Arrow Ambulance | | Medical Supply & Arabella Boutique | | Windsor Court |
| | Auditory Oral School | | Risk Management Company | | Windsor of Savoy |
| | Cancer Center/Mills Breast Cancer Institute | | | | |

Scope Exclusions

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Purpose

- A. Advances in and benefits from research depend on the reliability of the research record. The scientific enterprise relies on the integrity of researchers in proposing research and collecting, analyzing, and reporting research data. Research misconduct has far-reaching consequences. It not only can cost the researchers and staff their careers, but it also can do serious harm to the Carle Physician Group's reputation.
- B. The existence of research funding is not a factor in determining whether research misconduct exists, although the funding source may be a factor in the Carle Physician Group's procedure for responding to allegations of research misconduct.
- C. The primary responsibility for maintaining standards of intellectual integrity rests with individual researchers. However, the Carle Physician Group has a major role to play in three (3) respects:
 1. Providing an environment in which research can be conducted appropriately.
 2. Declaring the standards that must not be abrogated.
 3. Enforcing the standards on those occasions where violations may have occurred.
- D. The purpose of this document is to set forth the policies and procedures by which Carle Physician Group seeks to maintain and enforce such standards through impartial fact-finding and fair adjudication of allegations of research misconduct.
- E. The policy will be followed when an allegation of possible research misconduct is received by the Carle Physician Group unless particular circumstances dictate that, in the best interests of the Carle Physician Group, variation from the normal procedure is required. Any change from normal procedures must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation must be approved in advance by the Compliance Committee.

Definitions

- A. [Approved Terminology – AD100A](#) is a glossary of common terms that can be used in P & P's without defining them in the document.
- B. **Research Misconduct** – Fabrication, falsification, or plagiarism in proposing, performing or reviewing research

results and other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. Research misconduct does not include honest error or differences of opinion.

- C. **Research** – A systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific 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.
- D. **Research Record** – The record of data or results that embodies the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports and journal articles.
- E. **Fabrication** – Making up data or results and recording or reporting them.
- F. **Falsification** – 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.
- G. **Plagiarism** – Appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.
- H. **Good Faith** – Having a belief in the truth of an allegation or testimony that a reasonable person in the complainant’s or witness’s position could have based on the information known to the complainant or witness at the time. An allegation of research misconduct is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.
- I. **Retaliation** – Any action that adversely affects the employment or other institutional status of an individual because the individual has:
 - 1. Made a good faith allegation of research misconduct
 - 2. Made a good faith allegation of inadequate Carle Physician Group response to an allegation
 - 3. Cooperated with an investigation of such allegation
- J. **Recklessly** – A person consciously disregards a substantial and unjustifiable risk or grossly deviates from the standard of conduct that a reasonable individual would observe.
- K. **PHS** – The U.S. Public Health Service, an operating component of HHS that includes the following operating divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institute for Health, the Substance Abuse and Mental Health Services Administration, and the Offices of the Regional Health Administrators.
- L. **ORI** – The Office of Research Integrity, the office within the U.S. Department of Health and Human Services (HHS) that is responsible for the research misconduct and research integrity activities of the U.S Public Health Service.
- M. **Conflict of Interest** – The real or apparent interference of one person’s interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

Statement of Policy

- A. **Compliance Officer (CO):** The Corporate Compliance Officer shall have the primary responsibility for implementation of the procedure set forth in this policy.
- B. **Responsibility to Report Misconduct:**
 - 1. All Physicians and Staff will be responsible to report observed, suspected, or apparent research misconduct to the CO. If unsure whether a suspected incident falls within the definition of research misconduct, contact the CO to discuss the suspected misconduct informally.
 - 2. If the circumstances described by the individual do not meet the definition of research misconduct, the CO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.
 - 3. At any time, an individual may have confidential discussions and consultations about concerns of possible misconduct with the CO and will be counseled about appropriate procedures for reporting allegations.
- C. **Multiple Phases of the Response to an Allegation of Research Misconduct:** A response to an allegation of research misconduct consists of three (3) phases:
 - 1. Inquiry
 - 2. Investigation
 - 3. Adjudication
- D. **Protecting the Complainant:**
 - 1. The Carle Physician Group will take all reasonable and practical steps to protect the positions and reputations of any good faith complainant, witnesses and cooperating individuals and to protect them from retaliation in the terms and conditions of their employment or other status at the Carle Physician Group. The CO will review instances of alleged retaliation for appropriate action.¹

2. Physicians and Staff should immediately report any alleged or apparent retaliation to the CO.
 3. The CO will protect the privacy of those who report research misconduct in good faith to the maximum extent possible. For example, if a complainant requests anonymity, the CO will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws. The complainant will be advised that if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity may no longer be guaranteed.ⁱⁱ
- E. **Protecting the Respondent:** Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.ⁱⁱⁱ
- F. **Cooperation with Inquiries and Investigations:** Physicians and staff will cooperate with the CO and other Carle Physician Group officials in the review of allegations and the conduct of inquiries and investigations. Physicians and Staff have an obligation to provide relevant evidence to the requesting Clinic officials regarding allegations.
- G. **Findings of Research Misconduct:** A finding of research misconduct requires that:
1. There be a significant departure from accepted practices of the relevant research community;
 2. The misconduct be committed intentionally, or knowingly, or recklessly;
 3. The allegation be proven by a preponderance of evidence.^{iv}

Procedure

A. General Preliminary and Reporting Procedures:

1. **Preliminary Assessment of Allegations:** Upon receiving an allegation of research misconduct, the CO will immediately assess the allegation to determine whether PHS support or PHS applications for funding are involved and whether the allegation falls under the definition of research misconduct.^v
2. **Non-PHS Supported Research:** If the allegation of research misconduct does not involve PHS-supported research, then the government reporting procedures outlined in this policy will not apply. Instead, the Carle Physician Group will comply with any other applicable laws and with the contractual duties that it may owe to the research sponsor.
3. **Reporting to ORI:** If the allegation involves PHS support, the CO will report to the ORI as required by regulation to keep ORI apprised of any developments during the course of the inquiry or investigation in order to ensure appropriate use of federal funds and otherwise protect the public interest.^{vi} The CO will notify ORI at any stage of the inquiry or investigation^{vii} if:
 - a. There is an immediate need to protect humans.
 - b. There is an immediate need to protect federal funds or equipment or other interests.
 - c. Research activities should be suspended.
 - d. There is reasonable indication of possible violations of criminal law, in which case the CO must inform ORI within twenty-four (24) hours of obtaining information.
 - e. Federal action is required to protect the interests of those involved in the research misconduct proceeding.
 - f. The research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
 - g. The research community or public should be informed.
4. **Early Termination of Process:** If the Carle Physician Group plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the CO will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.^{viii}
5. **Admissions of Research Misconduct:** When PHS funding or applications for funding are involved and an admission of research misconduct is made, the CO will contact ORI for consultation and advice. When the case involves PHS funds, the Carle Physician Group cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.^{ix}
6. **Termination of Employment:** The termination of the respondent's employment, by resignation or otherwise, before or after an allegation of research misconduct has been reported, will not preclude or terminate the research misconduct procedures. If the respondent, without admitting to the research misconduct, elects to resign his or her position prior to the initiation of the inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the Compliance Committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.
7. **Interim Administrative Actions:** Carle Physician Group officials will take interim administrative actions, as appropriate, to protect federal funds and ensure that the purposes of the federal financial assistance are carried out.^x

8. **Retention of Consultants:** At any time during the research misconduct process, the Clinic may use the services of internal or external consultants. The Carle Physician Group will make sure that any consultant will have no real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to perform the service requested.

B. Inquiry Procedures:

1. **Initiation of the Inquiry:** Following the preliminary assessment, if the CO determines that the allegation provides sufficient information to support follow-up and falls under the definition of research misconduct, it will immediately initiate the inquiry process. In initiating the inquiry, the CO should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.^{xi}
2. **Sequestration of the Research Records:** After determining that an allegation falls within the definition of research misconduct, the CO must secure all original research records and evidence relevant to the allegation. The CO will give respondent copies of, or reasonable supervised access to, the research records. The CO also will undertake all reasonable efforts to take custody of additional research records and evidence discovered during the course of any proceeding.
3. **Notification:** The CO will prepare a charge that:
 - a. Describes the allegations and any related issues identified during the allegation assessment.
 - b. States that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation.

The CO will notify the respondent of the allegations of research misconduct within ten (10) business days of the decision to initiate an inquiry.

4. Inquiry Process:

- a. The CO typically will interview the complainant, the respondent, and key witnesses as well as examine relevant research records and materials and will evaluate the evidence and testimony obtained during the inquiry with the assistance of any expert consultants.
- b. The CO will determine whether there is sufficient evidence of possible research misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.^{xii}

5. Inquiry Report:

- a. The CO will prepare a written inquiry report that states the allegations; the PHS support, if any; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and the recommendations, including other actions that should be taken if an investigation is not recommended. Carle Physician Group counsel will review the report for legal sufficiency.^{xiii}
- b. The CO will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the complainant, if he or she is identifiable, with portions of the draft inquiry report that address the complainant's role and opinions in the investigation.^{xiv}
- c. The CO may establish reasonable conditions for review to protect the confidentiality of the draft report.
- d. Within fourteen (14) business days of their receipt of the draft report or excerpts from the draft report, the complainant and the respondent will provide their comments, if any, to the CO. Any comments that the complainant or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the CO may revise the report as appropriate.^{xv}

6. Inquiry Decision and Notification:

- a. The CO will normally complete the inquiry and submit a report in writing to the Compliance Committee no more than sixty (60) calendar days following the commencement of the inquiry. The CO will notify the respondent of any time extensions.^{xvi}
- b. The CO will transmit the final report and any comments to the Compliance Committee, which will determine whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is completed when the Compliance Committee makes this determination, which will be made within thirty (30) business days of its receipt of the final inquiry report. Any extension of this period will be based on good cause and recorded in the inquiry file.^{xvii}
- c. The CO will notify both the respondent and the complainant in writing of the Compliance Committee's decision of whether to proceed to an investigation. The notice to the respondent will include a copy of the inquiry report.^{xviii}

- d. Within thirty (30) days of finding that an investigation is warranted and before the investigation begins, the CO will forward to the ORI Director a copy of the inquiry report with notice of the Compliance Committee's decision to initiate an investigation. 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 numbers involved.^{xix}

C. Investigation Procedures:

1. **Purpose of the Investigation:** The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether research misconduct has been committed, by whom, and to what extent. The investigation also will determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.
2. **Notice of Investigation to Respondent:** Within fourteen (14) days of the Compliance Committee's decision to proceed with an investigation and before the investigation begins, the CO will notify the respondent in writing of the allegations. The CO will give the respondent written notice of any new allegations of research misconduct, within a reasonable time after a decision is made to pursue allegations not addressed during the inquiry or in the initial notice of investigation.^{xx}
3. **Sequestration of the Research Records:** The CO will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. The need for additional sequestration of records may occur for any number of reasons, including the Carle Physician Group's decision to investigate additional allegation not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.^{xxi}
4. **Appointment of the Investigation Committee:** Within thirty (30) days after the Compliance Committee determines that an investigation is warranted, the CO, in consultation with other Clinic officials as appropriate, will appoint an investigation committee and the committee chair. The investigation committee should consist of at least three (3) individuals who have no real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. Unless evidence of bias exists, the Chief Medical Officer will serve on all investigation committees. The other committee members may be physicians, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the Carle Physician Group. Individuals appointed to the investigation committee may also have served on the inquiry committee.^{xxii}
5. **Charge to the Committee:**
 - a. The CO will define the subject matter of the investigation in a written charge to the investigation committee that defines research misconduct, describes the allegations and related issues identified during the inquiry, and names the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred, and, if so, to what extent, who was responsible, and its seriousness.
 - b. During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the investigation committee will notify the CO, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.
6. **First Meeting:** The CO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions.
7. **Investigation Process:** The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the investigation committee should interview the complainant, the respondents, and other individuals who might have information regarding aspects of the allegations. The investigation committee will diligently pursue all significant issues and leads, including any evidence of additional instances of possible research misconduct. Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.^{xxiii}
8. **Elements of the Investigation Report:** The final report must contain the following information: the specific allegations; a description of the policies and procedures under which the investigation was conducted; a summary

of the research records and evidence reviewed and taken into custody but not reviewed; a finding for each separate allegation of research misconduct as to whether research misconduct did or did not occur and, if so:

- a. Identify whether the misconduct was falsification, fabrication, or plagiarism and if it was intentional, knowing or reckless disregard.
- b. Summarize the facts and the analysis that supports the conclusion and consider the merits of any reasonable explanation by the respondent.
- c. Identify the specific PHS support.
- d. Identify whether any publications need correction or retraction.
- e. Identify the persons responsible for the misconduct.
- f. List any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.
- g. Include and consider any comments made by the respondent and complainant.^{xxiv}

9. Comments on the Draft Report:

- a. *Respondent:* The CO will provide the respondent with a copy of the draft investigation report for comment and rebuttal and will provide a copy of or supervised access to evidence on which the investigation report is based. The respondent will be allowed ten (10) business days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.^{xxv}
- b. *Complainant:* The CO may provide the complainant with those portions of the draft investigation report that address the complainant's role and opinions in the investigation. The complainant will be allowed ten (10) business days to review and comment on the draft report. The report should be modified, as appropriate, based on the complainant's comments.^{xxvi}
- c. *Clinic Legal Counsel:* The draft investigation report will be transmitted to the Clinic's legal counsel for review of its legal sufficiency. Comments should be incorporated into the report as appropriate.
- d. *Confidentiality:* In distributing the draft report, or portions thereof, to the respondent and complainant, the CO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the recipient may be asked to sign a confidentiality agreement.

10. Compliance Committee Review and Decision:

- a. Based on a preponderance of the evidence, the Compliance Committee will make the final determination whether to accept the investigation report, its findings, and the recommended Carle Physician Group actions. The Compliance Committee also may return the report to the investigation committee with a request for further fact-finding or analysis. If the Compliance Committee's determination varies from that of the investigation committee, the Compliance Committee will explain in detail the basis for rendering a decision different from that of the investigation. The Compliance Committee's determination, together with the investigation committee's report, constitutes the final investigation report.^{xxvii}
- b. When a final decision on the case has been reached, the CO will notify both the respondent and the complainant in writing. In addition, the Compliance Committee will determine whether any other relevant parties, including law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, and collaborators of the respondent in the work, should be notified of the outcome of the case. The CO will be responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

11. Time Limit for Completing the Investigation Report: An investigation should ordinarily be completed within one hundred twenty (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 Compliance Committee for approval, and completing the final report.^{xxviii}

12. Request for Extension: If the Clinic determines that it will not be able to complete the investigation in one hundred twenty (120) days, the CO 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 CO will file periodic progress reports as requested by the ORI.^{xxix}

13. Reporting to ORI: The CO will notify the ORI of the final outcome of the investigation and provide ORI with a copy of the investigation report with attachments, including the respondent's and complainant's comments. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.^{xxx}

D. Adjudication Procedures^{xxxi}:

1. The Carle Physician Group will take appropriate administrative actions against individuals when an allegation of research misconduct has been substantiated.

2. If the Compliance Committee determines that the alleged research misconduct is substantiated by the findings, the Committee will decide on the appropriate actions to be taken, or will refer the matter as otherwise required by the Carle Physician Group's bylaws or professional staff policies. The actions may include but are not limited to:
 - a. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found.
 - b. Removal of the 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.
 - c. Restitution of funds as appropriate.

E. Miscellaneous Follow-Up Procedures:

1. **Restoration of the Respondent's Reputation:** If the Carle Physician Group finds no misconduct and ORI concurs, after consulting with the respondent, the Carle Physician Group will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Carle Physician Group may consider such actions as notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunging all reference to the research misconduct allegation from the respondent's personnel file. Any actions to restore the respondent's reputation must first be approved by the Compliance Committee.^{xxxii}
2. **Protection of the Complainant and Others:** Upon completion of an investigation, the Compliance Committee will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of the complainant.^{xxxiii}
3. **Allegations Not Made in Good Faith:** The CO will report to the Compliance Committee his/her recommendations regarding any evidence of bad faith allegations of research misconduct. The Compliance Committee will make findings regarding bad faith allegations. If an allegation is found to have been made in bad faith, the Compliance Committee will decide any additional administrative action to be taken against the complainant.
4. **Record Retention:** After completion of a case and all ensuing related actions, the CO will prepare a complete file, including the records of any inquiry or investigation and copies of all relevant documents. The Compliance Office will keep the file for seven (7) years after completion of any research misconduct or PHS proceedings, unless otherwise excepted by PHS regulation. On request, the Carle Physician Group must provide to HHS copies of any record relevant to research misconduct allegation that are needed to conduct an HHS inquiry or investigation or for ORI to conduct a review or to present evidence in any PHS proceeding under the PHS regulation.^{xxxiv}

Attachments N/A

Other Related Links N/A

References

- 42 U.S.C. § 389b; 42 C.F.R parts 50 and 93; 70 Fed. Reg. 28370 (May 17, 2005); ORI Model Policy for Responding to Allegations of Scientific Misconduct.

Electronic Approval on File

Michael W. Bukosky
Executive Vice President, Chief Administrative Officer

Kirk Moberg, MD
Senior Vice President, Chief Medical Officer

R. Bruce Wellman, MD
President, Chief Executive Officer
Signatory Official

ⁱ 42 C.F.R. § 93.304(a),(l)

ⁱⁱ 42 C.F.R. §§ 93.108; 93.304(a)

ⁱⁱⁱ 42 C.F.R. § 93.304(k)

^{iv} 42 C.F.R. §§ 93.104; 93.106

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- v 42 C.F.R. § 93.307(a)
 - vi 42 C.F.R. § 93.309
 - vii 42 C.F.R. §§ 93.304(d), (i); 93.318
 - viii 42 C.F.R. § 93.316
 - ix 42 C.F.R. §§ 93.304; 93.316
 - x 42 C.F.R. § 93.304(h)
 - xi 42 C.F.R. § 93.307(b), (c)
 - xii 42 C.F.R. § 93.307(d)
 - xiii 42 C.F.R. §§ 93.307(e); 93.309(a)
 - xiv 42 C.F.R. § 93.307(f)
 - xv 42 C.F.R. § 93.304(f)
 - xvi 42 C.F.R. § 93.307(g)
 - xvii 42 C.F.R. § 93.307(d)
 - xviii 42 C.F.R. 93.308
 - xix 42 C.F.R. §§ 93.304(d); 93.309(a); 93.310(b)
 - xx 42 C.F.R. § 93.310(c)
 - xxi 42 C.F.R. § 93.310(d)
 - xxii 42 C.F.R. § 93.310(f)
 - xxiii 42 C.F.R. § 93.310(e) – (h)
 - xxiv 42 C.F.R. § 93.313(a) – (g)
 - xxv 42 C.F.R. § 93.304(f); 93.312(a)
 - xxvi 42 C.F.R. § 93.312(b)
 - xxvii 42 C.F.R. § 93.104(c)
 - xxviii 42 C.F.R. § 93.311
 - xxix 42 C.F.R. § 93.311(b)
 - xxx 42 C.F.R. § 93.315
 - xxxi 42 C.F.R. § 93.304
 - xxxii 42 C.F.R. § 93.304(k)
 - xxxiii 42 C.F.R. § 93.304(l)
 - xxxiv 42 C.F.R. §§ 93.305(d); 93.309(b) – (c); 93.313(h); 93.317(b)