

**The Carle Foundation  
Research Policy 105**

<b>Subject</b>	Research Misconduct and Failures of Research Integrity				
<b>Approval</b>	Jan 2008	<b>Review</b>	Aug 2009	<b>Revision</b>	Aug 2009
<b>Purpose</b>	Carle Foundation Hospital (CFH) supports the conduct of research with the goal of increasing knowledge, discovering truth, and improving the lives and health of individuals and the community through improved understanding of health, disease and interventions. Integrity in research is critical to accomplishing this mission. The purpose of this Policy is to define actions which constitute Research Misconduct and Failure of Research Integrity and to describe the CFH investigational policies and procedures with respect to breaches in research integrity.				

**Policy Overview, Authority, and Definitions**

1. Research, invention, and discovery are important components of the CFH mission. The trust placed in CFH by our patients, our community, and our colleagues' demands that research be conducted in an open, creative, honest, and rigorous manner. Actions which call into question the integrity of research conducted at CFH betray that trust. This Policy describes the role of each individual in identifying and reporting potential Research Misconduct or other Failures of Research Integrity and describes the means by which CFH will maintain, investigate, and enforce research integrity standards.
2. CFH is committed to an environment that sustains integrity, ensures impartial fact-finding and fair determinations regarding allegations of breach in research integrity, and supports appropriate responses to those fact-finding results.
3. This Policy and its related procedures are intended to comply with federal regulatory requirements. Principles of basic fairness and confidentiality will be observed, but the procedures established are not intended to be equivalent to the rules applicable to judicial proceedings.

**Policy**

1. Research at CFH shall be conducted in accordance with generally accepted scientific and ethical principles. Each individual who is associated with CFH research has a personal obligation to maintain the highest standards of integrity and to report any good-faith concerns regarding possible breaches in integrity, including Research Misconduct. CFH will investigate any good-faith Allegation in accordance with federal regulations, principles of basic fairness, and this Policy, and take appropriate remedial action to ensure CFH research integrity.
2. **Definitions:**
  - a. *Allegation* means any written or oral statement or other indication of possible breaches in research integrity, including Research Misconduct and Failure of Research Integrity, made to a CFH administrator, manager, Compliance Officer, or via the compliance hotline, or which otherwise comes to the attention of the Executive Director of the Research Institute and the Clinical Director of the Research Institute.
  - b. *Breach in research integrity* means either Research Misconduct or a Failure in Research Integrity or both.
  - c. *Committee* shall mean the Inquiry Committee or Investigation Committee, as appropriate.
  - d. *Complainant* means a person who, in good faith, makes an Allegation of breach in research integrity.
  - e. *Conflict of interest* refers to a situation in which a real or apparent interference of one person's relationship or outside interests could lead to bias in actions or decisions. Conflicts of interest may occur due to prior or existing financial, personal or professional relationships.
  - f. *Failure of Research Integrity* means any of the following:
    - A material failure to comply with applicable federal requirements for protecting researchers, human participants, or the public, or for ensuring the welfare of laboratory animals;
    - A material failure to disclose all real or reasonably perceived conflicts of interest; or
    - An abuse of confidentiality or trust, such as the use or disclosure of ideas or preliminary data of others which were given with an expectation of confidentiality, for example, based on (i) access to privileged information through the opportunity for editorial review of manuscripts submitted to journals; or (ii) the opportunity for peer review of proposals by external entities or by internal committees, such as the Scientific Review Committee, the Institutional Review Board, or any similar committee through which one gains access to privileged research-related information.
  - g. *FDA* means the United States Food and Drug Administration.
  - h. *Good-faith Allegation* means an Allegation made with the honest belief that a breach in research integrity may have occurred. An Allegation is not in good-faith if it is made with reckless disregard for, or willful ignorance of, facts that would disprove the Allegation.

## Policy (cont.)

- i. *Inquiry* is the process of gathering information and conducting initial fact-finding to determine whether an Allegation or apparent instance of breach in research integrity demonstrates substance and warrants an Investigation.
- j. *Inquiry Committee* means the ad hoc committee charged with conducting an Inquiry.
- k. *Inquiry Report* means the document prepared by the Inquiry Committee which outlines the Inquiry process undertaken by the Committee, its findings, and its recommendations and which is reviewed by the Executive Director of the Research Institute, the Clinical Director of the Research Institute, and the Institutional Official.
- l. *Investigation* means the formal development of a factual record and the examination of that record leading to a decision as to whether Research Misconduct or Failure of Research Integrity has occurred and recommending consequences relative to such determination.
- m. *Investigation Committee* means the ad hoc committee charged with conducting an Investigation.
- n. *Investigation Report* means the document describing the Investigation undertaken by the Committee, its findings, and its recommendations which is prepared by the Investigation Committee and reviewed by the Executive Director of the Research Institute, the Clinical Director of the Research Institute, and the Institutional Official.
- o. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for research misconduct and the research integrity activities of the U.S. Public Health Service.
- p. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.
- q. *PHS Regulation* means the Public Health Service regulation set forth at 42 C.F.R. Part 50, Subpart A, titled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science," or as amended, which establishes standards for inquiries and investigations into Allegations of research misconduct related to PHS Supported Research.
- r. *PHS Support* means PHS grants, contracts, cooperative agreements, or applications therefore, including training grants.
- s. *Preliminary Assessment* means the initial review of the Allegations by the Executive Director of the Research Institute and the Clinical Director of the Research Institute to determine whether the Allegations (1) are clearly made in bad faith; or (2) if true, clearly do not relate to possible Research Misconduct or a Failure of Research Integrity. If any possibility presents that an Allegation made in good faith might, if true, constitute Research Misconduct or a Failure of Research Integrity, an Inquiry will be initiated.
- t. *Preponderance of the evidence* means informational proof that, when compared with opposing evidence, leads to the conclusion that the particular fact at issue is more probably true than not.
- u. *Research Misconduct* or *Misconduct in Research* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. A finding of Research Misconduct requires occurrence of a significant departure from accepted practices within the research or scholarly community; that the Research Misconduct be committed intentionally, knowingly, or recklessly; and that the Allegation be proven by a preponderance of the evidence.
  - *Fabrication* means contriving data or results and recording or reporting them.
  - *Falsification* means manipulating research materials, equipment, or processes; or changing or omitting data or results so 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.

*Research Misconduct* does not include:

  - An honest mistake
  - Honest differences in interpretation or value of data
  - Bona-fide scientific disputes or disagreements
  - Authorship disputes, unless the Allegation rises to the level of plagiarism
  - Failure to use good scientific method, unless the failure rises to the level of fabrication or falsification.
- v. *Research record* means any data or results embodying the facts resulting from scholarly inquiry including, but 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; digital images; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files. "Data or results" shall be interpreted broadly to encompass all forms of scholarly information about the research at issue, without regard to the type of recording or storage media, including, but not limited to, raw numbers, field notes, interviews, notebooks and folders, laboratory observations, computers

## Policy (cont.)

and other research equipment, CD-ROMs, hard drives, floppy disks, Zip disks, back-up tapes, machine counter tapes, research interpretations and analyses, tables, slides, photographs, charts, gels, individual facts, statistics, tissue samples, reagents, and oral representations of research results.

- w. *Researcher* means any person who conducts research at or through CFH or who is paid by, under the control of, or affiliated with the CFH (such as an affiliated investigator, business associate, intern, fellow, resident, faculty, scientist, technician, staff member, key research personnel, student, guest researcher, or collaborator at or with CFH).
- x. *Respondent* means a person against whom an Allegation is directed or a person whose actions are the subject of the Inquiry or Investigation. When any Inquiry or Investigation involves multiple Respondents, all references in this Policy to "Respondent" shall also be read in the plural, as appropriate.
- y. *Retaliation* means any action taken by CFH (or its agents or employees) or another individual (e.g., Respondent) that adversely affects the employment or other status of an individual at CFH because that individual has, in good-faith, made an Allegation or has cooperated in good-faith with an Investigation of an Allegation.

### 3. Applicability

- a. This Policy applies to all CFH employees and to Researchers who are not CFH employees but who conduct research at or supported by CFH or Carle Foundation. Research is "supported by" CFH or Carle Foundation if it uses CFH or Carle Foundation grant or other funding; CFH or Carle Foundation assets, resources, or business or medical records; or involves interaction with or observation of CFH patients, employees, staff, volunteers, medical staff members, or others associated with CFH or Carle Foundation. This policy does not apply to investigators with no CFH affiliation who interview or observe persons (including CFH employees) in a manner not touching or engaging CFH (does not occur at CFH, use CFH assets, etc.).

### 4. Duty to Report Suspected Research Misconduct or Failure of Research Integrity

- a. All employees of CFH and all researchers at, or supported by, CFH or Carle Foundation should report observed, suspected, or apparent Research Misconduct or possible Failure of Research Integrity to the Executive Director of the Research Institute, the Clinical Director of the Research Institute, a CFH administrator, manager, the Compliance Officer, or via the Compliance Hotline. Reports to the Compliance Hotline may be anonymous; however, in such case, CFH will be unable to offer Complainant certain rights otherwise available under this Policy. Any employee or researcher may, at any time, speak with the Executive Director of the Research Institute or the Clinical Director of the Research Institute about concerns regarding possible Research Misconduct or Failure of Research Integrity. The Executive Director of the Research Institute, the Clinical Director of the Research Institute, or a designee will advise the employee or researcher of his or her obligations and rights under this Policy and other related policies and will attempt to assist the employee or researcher in determining the proper course of action.

### 5. Duty to Cooperate

- a. All individuals, to whom this Policy applies, including individuals against whom an Allegation is made, are required (i) to cooperate with CFH and its employees and agents with respect to identifying and remedying any breach in research integrity and (ii) to comply with this Policy and its related procedures. Cooperation includes providing access to Research Records, agreeing to be interviewed, suspending alterations to or destruction of records or information related to the research in question, and refraining from engaging in behavior which could reasonably be perceived as Retaliation or which otherwise impairs the process set forth in this Policy.

### 6. Confidentiality

- a. The identity of a Respondent or a Complainant shall be disclosed only on a "need-to-know" basis or as required by law or regulation. To the extent possible, CFH will protect the confidentiality of Complainant and others involved with Allegations and any resulting Inquiry or Investigation, taking into consideration the need to protect research participants, to protect public health and safety, and to conduct a fair Inquiry and Investigation. However, confidentiality is not absolute. CFH may release information as necessary to ensure fairness, to protect public health, and to comply with law or regulation. CFH may also grant a Respondent's request to question the Complainant relative to the Allegations during an Inquiry or Investigation Committee meeting.

### 7. Obligation of Good Faith

- a. Ensuring research integrity requires that all individuals involved act in good faith. CFH will exercise diligence in protecting Complainants who make Allegations in good faith and in protecting the reputations of those who cooperate with an Inquiry or Investigation in good faith. In no event will Retaliation against a Good-faith Complainant, witness, or Committee member be tolerated. Disciplinary action may be taken against any individual who engages in Retaliation. Actions taken in bad faith may also result in the imposition of sanctions by CFH.

## Policy (cont.)

### 8. Conflicts of Interest

- a. At each stage of an Inquiry or subsequent Investigation, all persons involved shall be vigilant to prevent any real or perceived conflicts of interest or personal conflicts or relationships between colleagues from affecting the outcome of the proceedings and resolution of the charges. Possible Conflicts of interest may include co-authorship of work in the recent past with any individual directly involved with the alleged misconduct, or a professional or personal relationship with the Respondent beyond mere acquaintance or colleague. If such relationship is present, the individual with the Conflict shall refuse him/herself from any investigative or decisional role in the case. If, at any point in the process, any prospective Committee member presents a Conflict of interest, the Executive Director of the Research Institute or the Clinical Director of the Research Institute shall appoint a replacement for that individual. If the Executive Director of the Research Institute or the Clinical Director of the Research Institute has a Conflict of interest, the Chief Operating Officer (CEO) of CFH shall name the replacement who will carry out the functions required of the Executive Director of the Research Institute or the Clinical Director of the Research Institute under this Policy for the particular matter that involves a Conflict of interest. If necessity dictates that a replacement be appointed during the course of the process, the new appointee shall be fully informed as to earlier procedures and evidence, but it shall not be required that any of the process commence anew.

### 9. Role of Counsel and Other Experts

- a. CFH (including those acting on behalf of CFH in the investigatory process) may consult with counsel on procedural or substantive matters at any stage of the proceedings, and may, at the election of the Executive Director of the Research Institute or the Clinical Director of the Research Institute, include such counsel on the Committee, in which case alternative counsel with expertise in research shall provide impartial advice under paragraph 9.c. below. Respondents are free to consult with an attorney to represent their interests (at Respondent's cost). If CFH counsel is a member of the Committee, Respondent may have his or her own counsel attend any Committee meetings; however, the role of Respondent's counsel shall be limited to advising Respondent, and Respondent's counsel shall not be permitted to participate in the proceedings.
- b. CFH Counsel is responsible for:
  - Ensuring compliance with all applicable laws and regulations;
  - Monitoring the progress of the resolution of each Allegation to ensure adherence to CFH procedures;
  - General supervision of proceedings for the purpose of affording procedural fairness to the Complainant, the Respondent, and witnesses.
- c. CFH Counsel will not act as the prosecutor or defender of the Respondent but will act as an impartial legal advisor to CFH. Procedural questions from the Respondent, Complainant, or prospective witnesses may be referred through the Executive Director of the Research Institute or the Clinical Director of the Research Institute or his/her designee to CFH Counsel. Individuals serving on the Inquiry Committee or the Investigation Committee are encouraged to seek legal guidance from CFH Counsel regarding any procedural question, particularly in connection with the preparation of written reports of actions taken, or before any action is taken relative to any person believed to have made an accusation of misconduct in bad faith. Any contact with or inquiry to CFH from a lawyer, including contacts and inquiries emanating from legal representatives of any federal, state, or local agency, must be immediately referred to CFH Counsel.
- d. CFH may retain other experts, including scientific experts, to assist CFH in determining the standards of the relevant research community or to otherwise assist CFH in fulfilling its obligations under this Policy, other applicable policies, and applicable laws and regulations. Respondent may also consult scientific experts (at Respondent's cost), but the Committee shall have the right to determine whether the opinion of such expert will be presented in person or through documentary evidence.

### 10. Research Misconduct versus Failure of Research Integrity

- a. Allegations of Failure of Research Integrity may be, but are not required to be, reviewed and evaluated in accordance with this Policy. The Executive Director of the Research Institute or the Clinical Director of the Research Institute or his/her designee shall be responsible for determining whether a Failure of Research Integrity is to be reported to ORI, FDA and/or funding agencies or sponsors of affected Research. If the Allegation is disproved or determined to not constitute Research Misconduct or a Failure of Research Integrity, CFH will work with the Respondent to help prevent any negative consequences from the Inquiry and/or Investigation.
- b. **ORI Intervention**  
The Executive Director of the Research Institute or the Clinical Director of the Research Institute or his/her designee may request technical or other assistance from ORI at any time and at his/her discretion. ORI has the right to intervene in an Investigation at its discretion.

## Procedures

### 1. Preliminary Assessment of Allegations

- a. Upon receiving an Allegation, the Executive Director of the Research Institute or the Clinical Director of the Research Institute will conduct a Preliminary Assessment of the Allegation to determine whether sufficient evidence exists to warrant an Inquiry and whether the Allegation falls under the definition of Research Misconduct or Failure of Research Integrity. The Executive Director of the Research Institute or the Clinical Director of the Research Institute may use the Preliminary Assessment to determine whether the Allegations (1) were clearly made in bad faith; or (2) if true, clearly do not relate to possible Research Misconduct or a Failure of Research Integrity. The Executive Director of the Research Institute or the Clinical Director of the Research Institute may consult with CFH Counsel or other appropriate individuals during this preliminary assessment.
- b. The Executive Director of the Research Institute or the Clinical Director of the Research Institute shall maintain a written record reflecting (1) the nature of the Allegation(s); (2) the individuals with whom the Executive Director of the Research Institute or the Clinical Director of the Research Institute conferred in conducting the Preliminary Assessment; and (3) if the determination is that the Allegation is without basis or outside the scope of this Policy, a clear and unequivocal basis for the determination.
- c. Only Allegations which are clearly without basis or outside the scope of the definition of Research Misconduct or Failure of Research Integrity will be resolved at this stage. If any possibility exists that a Good-faith Allegation might, if true, constitute Research Misconduct, an Inquiry will be initiated. If any possibility exists that a Good-faith Allegation might, if true, constitute a Failure of Research Integrity, the Executive Director of the Research Institute or the Clinical Director of the Research Institute has at his/her discretion the option of conducting an Inquiry under this policy or otherwise resolving the matter in a fair, professional, and expeditious matter according to policy section 9.a) above.

### 2. Conducting the Inquiry

#### a. Initiation and Purpose of the Inquiry

- The goal of an Inquiry is to determine whether an Allegation is sufficiently credible and specific so as to permit evaluation of evidence of potential Research Misconduct or Failure of Research Integrity, and to quickly dispel frivolous, bad-faith, or mistaken Allegations not otherwise addressed in the Preliminary Assessment. An Inquiry is a preliminary evaluation of the available evidence and testimony to determine whether sufficient evidence of possible Research Misconduct or Failure of Research Integrity exists to warrant an Investigation.
- The findings of the Inquiry will be set forth in an Inquiry Report. While it is not the purpose of the inquiry to reach a final conclusion about what definitely occurred or who was responsible, Allegations of Failure of Research Integrity may be resolved at this point or may proceed to an Investigation, based on the evidence and at the discretion of the Executive Director of the Research Institute or the Clinical Director of the Research Institute or his/her designee. However, Allegations of Research Misconduct demonstrating sufficient evidence to warrant an Investigation will proceed to an Investigation.
- If, after the Preliminary Assessment, the Executive Director of the Research Institute or the Clinical Director of the Research Institute believes an Inquiry is appropriate, he/she will provide the Respondent with written notice of the Allegations and the initiation of an Inquiry which clearly identifies the original Allegations and any related issues.

#### b. Sequestration of the Research Records

- Upon determining that an Inquiry is indicated and before sending the Notice of Inquiry to the Respondent, the Executive Director of the Research Institute or the Clinical Director of the Research Institute will promptly secure in a confidential manner all original Research Records and materials relevant to the Allegation. As appropriate, evidence will be sequestered in a manner which permits continued use of the relevant data, equipment, records or copies thereof, but which safeguards the evidence in the condition in which it existed on the date the Inquiry commenced.

#### c. Inquiry Process

- The Inquiry may be conducted by the Executive Director of the Research Institute or the Clinical Director of the Research Institute upon a review of readily available evidence or may be considered by an Inquiry Committee convened by the Executive Director of the Research Institute or the Clinical Director of the Research Institute. If the Executive Director of the Research Institute or the Clinical Director of the Research Institute deems further evidence necessary to complete the Inquiry, the Executive Director of the Research Institute or the Clinical Director of the Research Institute will appoint an Inquiry Committee to conduct the Inquiry and prepare the Inquiry Report as described in this Policy. The Inquiry Committee will consist of at least three (3) individuals who do not have real or apparent Conflicts of interest in the case, who are unbiased, and who have the necessary expertise to conduct the Inquiry. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons from inside or outside the institution. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will designate one member of the Inquiry Committee to act as the chair.

## Procedures (cont.)

- The Executive Director of the Research Institute or the Clinical Director of the Research Institute will, absent unusual circumstances, notify the Respondent in writing of the proposed Inquiry Committee membership within one (1) business day of its appointment. If Respondent objects to one or more members of the Inquiry Committee, the Respondent will submit a written objection, including reasons for the objection, to the Executive Director of the Research Institute or the Clinical Director of the Research Institute, the Compliance Officer, or the CEO of CFH within forty-eight (48) hours following receipt of notification of composition of the Committee. The Executive Director of the Research Institute or the Clinical Director of the Research Institute shall, in consultation with the Institutional Official, determine whether to replace the challenged member with an eligible substitute within three (3) business days after receipt of the written objection. In the event the Executive Director of the Research Institute or the Clinical Director of the Research Institute determines that replacement of the member in question is not indicated, the Executive Director of the Research Institute or the Clinical Director of the Research Institute shall so advise the Respondent in writing. If the Executive Director of the Research Institute or the Clinical Director of the Research Institute agrees to replace the challenged Committee member, the Respondent shall be advised of the identity of the replacement Committee member in writing.
- The Inquiry Committee shall request and review evidence, interview the Complainant and other individuals possessing relevant knowledge, and otherwise gather facts to determine whether sufficient credibility exists to warrant an Investigation. The Inquiry Committee will then prepare a draft Inquiry Report and submit it to the Executive Director of the Research Institute or the Clinical Director of the Research Institute. The Inquiry Committee may request guidance from the Executive Director of the Research Institute or the Clinical Director of the Research Institute in carrying out these responsibilities.

### 3. The Inquiry Report

- a. Elements of the Inquiry Report. A written Inquiry Report will be prepared by the Inquiry Committee and submitted to the Executive Director of the Research Institute or the Clinical Director of the Research Institute for Research that sets forth:
  - The specific Allegation(s);
  - The identity of each expert or consultant who participated in the Inquiry;
  - The PHS support, if any, associated with the research in question;
  - A summary of the Inquiry process;
  - A list of the research records reviewed;
  - Summaries of any interviews;
  - A description of the evidence in appropriate detail; and
  - A recommendation as to whether an Investigation should be conducted and whether any other actions should be taken if an Investigation is not recommended.
- b. Comments on the Draft Report by the Respondent and the Complainant
  - The Executive Director of the Research Institute or the Clinical Director of the Research Institute will provide the Respondent with a copy of the draft Inquiry Report for comment.
  - The Executive Director of the Research Institute or the Clinical Director of the Research Institute may provide the Complainant a summary of the Inquiry findings for comment, if deemed appropriate.
  - The Complainant and Respondent will provide their comments, if any, to the Executive Director of the Research Institute or the Clinical Director of the Research Institute within fourteen (14) calendar days after receiving the draft report or summary. Any comments submitted will become part of the final Inquiry Report and record. The Executive Director of the Research Institute or the Clinical Director of the Research Institute may, as deemed appropriate by the comments received, revise and finalize the draft report.
- c. Confidentiality of the Inquiry Report. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will establish reasonable conditions for review which protect the confidentiality of the draft report.

## Inquiry Decision and Notification

1. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will transmit the final Inquiry Report with his/her recommendations to the Institutional Official. In the event the Executive Director of the Research Institute or the Clinical Director of the Research Institute and the Institutional Official disagree regarding the need for an Investigation, an Investigation shall be commenced.
2. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will notify the Respondent, the Complainant, and all appropriate CFH officials in writing of the decision to proceed with an Investigation.

### **Inquiry Decision and Notification (cont.)**

3. The Inquiry process should be complete and the final report submitted to the Institutional Official no more than sixty (60) calendar days following the initiation of the Inquiry, unless circumstances warrant a longer period. In that instance, an extension may be granted for good cause, and the circumstances warranting a longer period will be entered into the records of the case and the Inquiry Report.
4. In the event a decision not to initiate an Investigation is rendered, detailed documentation of the Inquiry and the reasons for such decision shall be retained for a minimum of seven years and provided to ORI upon request.
5. In the event the Executive Director of the Research Institute or the Clinical Director of the Research Institute concludes that no Research Misconduct occurred but that there has been a Failure of Research Integrity, the Executive Director of the Research Institute or the Clinical Director of the Research Institute may, at his/her discretion, either order an Investigation or impose disciplinary actions against the responsible individual. Strict compliance with this Policy is not required in the case of an Investigation of a possible Failure of Research Integrity. However, to the extent that an Investigation is undertaken, it should be guided by this policy to afford the Respondent due process and to maintain appropriate records.
6. The Institutional Official shall notify ORI of a decision to initiate an Investigation for Research Misconduct within thirty (30) days of such decision.

### **Conducting an Investigation**

1. Purpose of an Investigation. The purpose of an Investigation is to explore in detail the Allegations, to examine the evidence in depth, and to determine whether Research Misconduct or a Failure of Research Integrity has been committed, by whom it was committed, and to what extent. The Investigation will also determine whether additional instances of possible Research Misconduct exist that would justify broadening the Investigation beyond the initial Allegations. This is particularly important where the alleged Misconduct involves clinical trials or potential harm to human subjects or the general public or when 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. Sequestration of the Research Records. If any additional pertinent Research Records or other evidence that were not previously secured during the Inquiry are identified, the Executive Director of the Research Institute or the Clinical Director of the Research Institute shall promptly secure such records or information in a confidential manner. The need for additional sequestration of records or information may occur for any number of reasons, including the decision to investigate additional Allegations not considered during the Inquiry stage or the identification of records that had not been previously secured during the Inquiry process.
3. Appointment of the Investigation Committee. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will consult with the Chair of the Institutional Review Board, the Institutional Official, and the Directors of the Human Subject Protection and the Research Office, and will appoint an Investigation Committee, naming one individual as the Committee chair. The Investigation Committee will consist of at least three (3) individuals who do not have real or apparent Conflicts of interest in the case, who are unbiased, and who have the necessary expertise to evaluate the evidence and issues related to the Allegations, to interview the Complainant, Respondent, key witnesses, and others having information which the Committee believes will be helpful, and to conduct the Investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons from inside or outside the institution.
4. Notice of Committee; Objection to Committee Member. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will ordinarily notify the Respondent in writing of the proposed Committee membership within three (3) business days of its appointment. If the Respondent objects to one (1) or more members of the Investigation Committee, the Respondent will, within two (2) business days after receipt of notification of composition of the Committee, submit to the Executive Director of the Research Institute or the Clinical Director of the Research Institute a written objection describing a valid basis for such objection. After consultation with appropriate CFH personnel and within five (5) business days after receipt of the written objection, the Executive Director of the Research Institute or the Clinical Director of the Research Institute will determine whether to replace the challenged member with an eligible substitute.
5. Charge to the Committee and the First Meeting
  - a. Charge to the Committee. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will define the subject matter of the Investigation in a written charge to the Committee which describes the Allegations and related issues identified during the Inquiry, defines Research Misconduct (and/or Failure of Research Integrity), and identifies the name of the Respondent. The charge will state that the Committee is to evaluate testimony of the Respondent, Complainant, and key witnesses and other evidence to determine whether, based on a preponderance of the evidence, Research Misconduct and/or Failure of Research Integrity occurred and, if so, to what extent, who was responsible, and its seriousness. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will provide the Respondent with a copy of the charge to the Committee.

## Conducting an Investigation (cont.)

- b. The First Meeting. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will convene the first meeting of the Investigation Committee to review the charge, the Inquiry Report, and the procedures and standards for conducting the Investigation, including confidentiality requirements and development of a specific investigation plan. The Investigation Committee will be provided with a copy of this Policy and, where PHS funding is involved, the PHS regulation.
6. Investigation Process.
- a. The Investigation Committee will ordinarily be appointed and the Investigation process initiated within thirty (30) days of the completion of the Inquiry.
  - b. The purpose of the Investigation is to assemble evidence relevant to the Allegations and to evaluate that evidence in a fair, unbiased, independent, objective and thorough manner.
  - c. The Investigation will normally involve examination of all relevant documentation, including, as applicable but not necessarily limited to, Research Records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the Committee will interview the Complainant, the Respondent, and other individuals who might have information regarding the Allegations or the conduct of the research in question. Interviews of the Respondent should ordinarily be tape recorded or transcribed, unless Respondent refuses. All other interviews should ordinarily be transcribed, tape recorded, or summarized. For major witnesses, 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. Revisions shall be limited to technical corrections and shall not be used as a means of altering or changing testimony.
  - d. The Investigation Committee will conduct a careful review of the Allegations, affording a fair opportunity to all individuals involved to present their knowledge and information to the Committee. The Investigation Committee may consider it necessary to review all research with which the Respondent is involved, or the Executive Director of the Research Institute or the Clinical Director of the Research Institute may direct the Investigation Committee to do so. Other areas of professional misconduct (e.g., clinical practice, personnel supervision, human or animal subjects research, or personal interaction) may be investigated as well, if the Investigation Committee has reason to believe or uncovers evidence that a broader range of misconduct has occurred. If, in the course of the Investigation, the Investigation Committee finds reasonable grounds to believe an Inquiry into actions of individuals other than the Respondent is warranted, it must promptly notify the Executive Director of the Research Institute or the Clinical Director of the Research Institute.
  - e. At the initiation of the Investigation, the Executive Director of the Research Institute or the Clinical Director of the Research Institute or a designee must inform each Respondent in writing of all the Allegations against her or him, the source of the Allegations, and the fact that an Investigation is taking place. The Respondent must be informed promptly and in writing of any amendment or addition to the original Allegations. Notice to the Respondent will include a provision prohibiting Retaliation against any individual known or suspected to be the Complainant or others involved, or otherwise interfering with the Investigation.
  - f. The Investigation Committee will give the Respondent written notification of the place, time, and date of any meeting at which her/his appearance is requested. Every effort will be made to schedule such meetings at a mutually convenient time. The Respondent may request a rescheduling of the meeting(s) with the Investigation Committee for good cause; however, repeated changes to schedules will not be permitted. Failure or refusal on the part of the Respondent to meet with the Investigation Committee will not deter the progress of the Investigation. If the Respondent is no longer affiliated with CFH, the requirements of written notice and the opportunity to answer the Allegations will be observed to the extent deemed practical, but failure of the Respondent to respond or to make her/himself available to those with investigatory responsibilities will not deter the Inquiry and Investigation.
  - g. All relevant materials and documents sequestered during either an Inquiry or an Investigation shall be secured in the office of the Executive Director of the Research Institute or the Clinical Director of the Research Institute or another location designated by the Executive Director of the Research Institute or the Clinical Director of the Research Institute throughout the course of the Inquiry and/or Investigation.
  - h. The Respondent may present a written statement at the start of the Investigation. He or she may request that the Investigation Committee interview certain individuals possessing relevant information and may suggest to the Investigation Committee any avenues of inquiry that he or she believes are likely to produce relevant evidence. The Respondent may request an opportunity to question the Complainant at a Committee meeting before the Committee completes its final report. If, however, in the judgment of the Executive Director of the Research Institute or the Clinical Director of the Research Institute, this would impose undue hardship on individuals involved, the face-to-face meeting may be denied.
  - i. If the research in question is supported by PHS, the Investigation Committee will work diligently to complete the Investigation and prepare the final report within 120 days after the commencement of the Investigation. If the Investigation Committee is unable to so complete the Investigation and final report within that timeframe, it shall

## Conducting an Investigation (cont.)

advise the Executive Director of the Research Institute or the Clinical Director of the Research Institute, who shall notify ORI and request an extension. Regardless of the funding source, the Investigation Committee will work diligently to complete the Investigation in a reasonable period of time.

- j. Documentation of the Investigation shall be created and maintained with sufficient thoroughness and detail to permit oversight and evaluation of both the process and the decision reached. Documentation relative to the Investigation shall be considered confidential and protected from disclosure, except as permitted or required by the Policy or law.
- k. At the conclusion of the Investigation, a report will be prepared which will include the names of the persons interviewed; a summary of the interviews; a description of the documents, data, and other evidence examined by the Investigation Committee; and the Committee's conclusion regarding each Allegation. The Respondent will, and the Complainant may at the discretion of the Executive Director of the Research Institute or the Clinical Director of the Research Institute, be given a copy of the Investigation Committee's draft report or (in the case of Complainant) relevant sections of that report. The Respondent, at the discretion the Executive Director of the Research Institute or the Clinical Director of the Research Institute, may also be given a copy of or supervised access to the evidence on which the report is based. Comments by the Respondent or Complainant shall be submitted to the Executive Director of the Research Institute or the Clinical Director of the Research Institute within 30 days after receiving their respective draft or summary report and shall be considered by the Investigation Committee in preparing the final report. The final report will be given to the Executive Director of the Research Institute or the Clinical Director of the Research Institute, along with the Respondent's comments, if any, and a copy will be provided to ORI in cases over which it has jurisdiction.
- l. As appropriate, any agency or organization that is supporting, considering support of, or has supported the research in question may be informed that an Investigation is taking place. For PHS-sponsored research, the report will be submitted to ORI, which may then inform relevant federal sponsors in accordance with ORI policies and procedures and consistent with the applicable sponsor rules, without identifying the Respondent. As appropriate and in accordance with any applicable regulatory requirements, the funding agency or organization (if other than a PHS agency) and ORI will be kept informed of progress throughout the Investigation.
- m. At any stage in the Investigation and after consultation with the Investigation Committee, the Executive Director of the Research Institute or the Clinical Director of the Research Institute may take steps to notify additional parties who, in his/her judgment, should be informed of the ongoing Investigation. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will also take interim administrative action as necessary to protect research staff, participants or others, or any sponsored project funding to assure that the intended purposes of the sponsored research in question are being carried out.
- n. If, at any stage in the Inquiry or Investigation of cases involving PHS-sponsored research, it is determined that any of the following conditions exist, the Executive Director of the Research Institute or the Clinical Director of the Research Institute will immediately notify ORI:
  - Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
  - HHS resources or interests are threatened;
  - Research activities should be suspended;
  - Reasonable indication of possible violations of civil or criminal law exist;
  - Federal action is required to protect the interests of those involved in the Investigation proceeding;
  - The Executive Director of the Research Institute or the Clinical Director of the Research Institute or a designee believes premature public disclosure of the Investigation proceeding is likely (so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved);
  - The research community or public should be informed.
- o. If it appears likely that a criminal act may have occurred, this must be reported immediately to appropriate legal counsel for CFH and the CFH Compliance Officer, either of whom may, upon request by CFH administration, assume responsibility for prompt notification of the appropriate federal, state, and local authorities.
- p. If the Investigation concludes that Research Misconduct and/or Failure of Research Integrity has not occurred and the Executive Director of the Research Institute or the Clinical Director of the Research Institute concurs with that conclusion, the matter will be closed and appropriate action taken to restore the reputation of all those involved in the investigation and to protect them against retaliation. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will retain the records of the Investigation, including the findings of the Investigation Committee, in a confidential, sequestered file for a period of seven years. The Executive Director of the Research Institute or the Clinical Director of the Research Institute will send a copy of the Investigation Committee's findings of no misconduct to the Institutional Official, to the Respondent, and to ORI.

## Conducting an Investigation (cont.)

- q. If, with due regard to whistleblower protections, the Inquiry or Investigation Committee finds: 1) the Allegations were based on information that the Complainant knew or should have known was without substantial basis and, 2) the Complainant acted in bad faith and with intent to damage the Respondent, appropriate disciplinary action shall be taken against those responsible in accordance with applicable procedures.
- r. If the Investigation Committee concludes that Research Misconduct and/or Failure of Research Integrity has occurred, a written report will be prepared and will include:
- A description of each Allegation considered;
  - A description of any PHS Support applicable to the research under review;
  - A copy of this Policy and related procedures;
  - An identification and summary of evidence considered and any evidence proffered but not evaluated in the Investigation;
  - A statement outlining the validity of each Allegation;
  - A determination of the type of Research Misconduct or Failure of Research Integrity involved,
  - A determination whether the misconduct was intentional, knowing, or in reckless disregard;
  - A summary of the facts and analyses supporting the determination and a discussion of the merits of any explanation offered by Respondent;
  - An identification of PHS support with respect to each Allegation;
  - A statement regarding the need for retraction of any publication based on the research in question;
  - An identification of each person responsible for the misconduct;
  - Any current or pending non-PHS federal support or applications for support by the person responsible for misconduct.
- s. The Executive Director of the Research Institute or the Clinical Director of the Research Institute or a designee will review the report and may question both the Investigation Committee and the Respondent. The Executive Director of the Research Institute or the Clinical Director of the Research Institute or a designee will accept or reject the Investigation Report in whole or in part. If the Investigation Report is rejected in whole or in part, the basis for such rejection shall be provided to the Investigation Committee, who shall consider the concerns and address them as appropriate. If the Executive Director of the Research Institute or the Clinical Director of the Research Institute rejects the revised report, the Institutional Official shall assume responsibility for developing an Investigation Report acceptable to both the Investigation Committee and the Institutional Official. If the Executive Director of the Research Institute or the Clinical Director of the Research Institute accepts the report, he/she will determine, in consultation with the Institutional Official, the actions to be taken. The report and other relevant information will be considered confidential but may be shared with other CFH personnel as appropriate.
- t. Recommendations of actions to be taken may include one or more of the following corrective and/or disciplinary actions:
- Withdrawal or correction of papers and abstracts;
  - Notification directed to editors of journals where fraudulent or suspect research has been published or is under review;
  - Notification of sponsoring agencies;
  - Termination or alteration of employment status, including imposition of disciplinary actions or periods of supervised probation;
  - Postponement or denial of promotion or advancement;
  - Release of information about the incident to the public, particularly when public funds were used to support the fraudulent or suspect research; or
  - Any other action deemed appropriate to the circumstances
- u. Notification to ORI. If the Investigation found Research Misconduct involving PHS-supported research, the Executive Director of the Research Institute or the Clinical Director of the Research Institute shall ensure that ORI receives a copy of the final Investigation Report, including all attachments; a statement regarding the Institution's final determination relative to the existence of Research Misconduct and the person responsible; and any completed, pending, or proposed administrative actions against such individual. CFH and all individuals affiliated with CFH shall cooperate with ORI as it evaluates the process and the determination and conducts any necessary oversight activities.
- v. Medical Staff Members. If the Respondent or a bad-faith Complainant is a member of the Medical Staff, the final report may be forwarded to the Chief of the Medical Staff for appropriate disciplinary actions in accordance with the Medical Staff process.

**Conducting an Investigation (cont.)**

7. Exclusivity of Procedure

- a. This procedure for the resolution of Research Misconduct is the exclusive mechanism within CFH and its subsidiaries and affiliates for adjudication of questions involving Research Misconduct other than actions which may be taken by the Medical Staff against its members. A person disciplined under this procedure may not invoke CFH's grievance procedure or any other recourse in an effort to gain a re-adjudication of the charge.

**Approval on File**

Anna Keck, PhD  
Executive Director of the Research Institute

William Schuh, MD, PhD  
Medical Director of the Research Institute