

**The Carle Foundation
IRB Policy 903**

Subject	Scientific Misconduct and Investigations				
Approval	Dec 2006	Review	Jun 2009	Revision	Jun 2009
Scope	These policies and procedures apply to all research conducted by Carle Investigators or at Carle facilities.				
Purpose	To ensure ethical conduct of research activities involving human subjects.				

Statement of Policy

1. It is the obligation of scientists to comply with the laws and relevant ethical principles in the conduct of research. The Carle IRB will be receptive to, and act on good faith allegations of misconduct in science. Such allegations must be reported to the Office of the Carle IRB for handling under CFH policies.

Specific Policies

1. Definitions

- a. "Act" means the Public Health Service Act, as amended, (42 U.S.C. 201, et seq.).
- b. "Inquiry" means information gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.
- c. "Investigation" means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.
- d. "Scientific Misconduct" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.
- e. "OSI" means the Office of Scientific Integrity, a component of the Office of the Director of the National Institutes of Health (NIH), which oversees the implementation of all PHS policies and procedures related to scientific misconduct, monitors the individual investigations into alleged or suspected scientific misconduct conducted by institutions that receive PHS funds for biomedical or behavioral research projects or programs, and conducts investigations as necessary.
- f. "OSIR" means the Office of Scientific Integrity Review, a component of the Office of the Assistant Secretary for Health, which is responsible for establishing overall PHS policies and procedures for dealing with misconduct in science, overseeing the activities of PHS research agencies to ensure that these policies and procedures are implemented, and reviewing all final reports of investigations to assure that any findings and recommendations are sufficiently documented. The OSIR also makes final recommendations to the Assistant Secretary for Health on whether any sanctions should be imposed and, if so, what they should be in any case where scientific misconduct has been established.
- g. "PHS" means the Public Health Service, an operating division of the Department of Health and Human Services (HHS). References to PHS include organizational units within the PHS that have delegated authority to award financial assistance to support scientific activities, e.g., Bureaus, Institutes, Divisions, Centers or Offices.
- h. "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

2. Scientific Misconduct and Other Concerns

- a. The Carle IRB strongly encourages any individuals with concerns regarding the protection of human research participants or the conduct of research at Carle Foundation Hospital, or any affiliate facility related to Carle Foundation Hospital, to report such concerns to the Office of the Carle IRB, regardless of whether such concerns implicate these Scientific Misconduct policies.
- b. **Allegation**
 - An allegation of scientific misconduct will be a written statement describing grounds for the allegation and submitted to the Carle IRB.
 - If requested, Carle IRB will, to the extent possible, shield from disclosure the name of the individual(s) reporting a concern regarding the protection of human subjects and/or the conduct of research under the Carle IRB's jurisdiction.
 - The Carle IRB has the authority to implement at any time restrictions or processes intended to protect human research subjects.
 - Upon receipt of an allegation, the Chair of the Carle IRB will designate an individual or individuals to conduct an appropriate inquiry. The inquiry will be completed within 60 calendar days from receipt of allegation. The allegation and inquiry will be kept confidential. All rights to due process will be given to the affected

Specific Policies (cont.)

individual. The affected individual will first be allowed an opportunity to comment on the allegations and inquiry. A written report will be submitted to the Carle IRB. The inquiry must be documented and filed for at least three years.

c. Investigation

- If the Carle IRB decides that the allegation and subsequent inquiry justify an investigation, the investigation will begin within 30 calendar days after completion of the inquiry. The investigation will be completed within 120 calendar days. The investigation will be documented and kept on file for at least three years.
 - The Carle IRB will attempt to select impartial experts to conduct the investigation. Any member of the Carle IRB with a conflict of interest will excuse himself or herself.
 - The investigation will be kept confidential. The affected individual will be allowed an opportunity to comment on the investigation.
 - The OSI will be notified immediately that an investigation will be conducted.
- The Carle IRB shall report to OSI within twenty-four (24) hours in the event that:
 - There is an immediate health hazard involved;
 - 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;
 - It is probable that the alleged incident is going to be reported publicly; or
 - There is a reasonable indication of possible criminal violation.

The Carle IRB will advise the OSI of developments that disclose facts that may affect funding for the individual. The Carle IRB will also take appropriate actions to protect Federal funds and to ensure that the purposes of the financial assistance will be carried out.

- d. **Unproven Allegations.** If the allegations are not proven, the Carle IRB will make every effort to restore the reputation of the individual accused of misconduct. The Carle IRB will also protect the reputation of the accuser when the allegation has been made in good faith.
- e. **Confirmed Misconduct.** If the investigation confirms misconduct, the Carle IRB will prepare a draft report. The report will address both disciplinary action for scientific fraud and whether the person(s) involved are to continue as responsible members of the Foundation. This report will be sent to the individual(s) accused of misconduct. Those persons will have ten days to respond. The Carle IRB will impose appropriate sanctions, which may include the following:
 - The research project will be suspended.
 - The Carle IRB will inform the individual's employer, university department, or other supervisory entity.
 - The Carle IRB will consider whether or not to report the results of the investigation to the Department of Professional Regulation that governs medical licensure.
- f. **Final Report.** A final report on the investigation will be submitted to the OSI.
- g. **Appeal.** An appeal may be submitted to a committee comprised of the Chief Executive Officer of the Carle Foundation, the Medical Director for Research, and the Executive Director for Research. This committee has the authority to modify or revise the sanctions taken by the Carle IRB.

3. Failure to Comply With Regulations or Carle IRB Policies

- a. Any individual who becomes aware of or has legitimate reason to suspect a failure of an Investigator to comply with research-related regulations and/or Carle IRB policies shall promptly advise the Carle IRB and appropriate Carle Foundation Hospital administrators, and governmental regulators as appropriate.
- b. In the event of a failure of an Investigator or research staff to comply with regulations or Carle IRB policies, or if an Carle IRB receives a report of such failure, the Carle IRB shall promptly investigate the allegations to determine whether such failure occurred, and the impact of such failure on human subject protection and the integrity of the research program.
- c. If the Carle IRB determines that there has been a failure to comply with Carle IRB regulations or policies, the Carle IRB may impose sanctions as appropriate to the individual, the nature of the failure, and the need to protect human subjects, including suspension or termination of the research project.
- d. In the event that serious or continuing failure to comply with regulations or Carle IRB policies is identified, the Carle IRB will determine what information should be provided to participants, based on whether the information might change the participant's willingness to participate in the research project or otherwise impact research participant rights.

Specific Policies (cont.)
e. The Chairperson of the Carle IRB shall advise the Institutional Official of any finding of serious or continuing non-compliance. The Chairperson and the Institutional Official shall coordinate the reporting of any serious or continuing noncompliance to appropriate state or federal agencies, Sponsors, the FDA and/or OHRP, as the case may be, in accordance with statutory or regulatory mandates.
Reference
http://ori.dhhs.gov/ (Office of Research Integrity website), and Carle IRB Policies
Approval On File

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