

# The Carle Foundation

## Research Policy 103

<b>Subject</b>	Conflicts of Interest in Research				
<b>Approval</b>	Sep 2005	<b>Review</b>	Feb 2011	<b>Revision</b>	Feb 2011
<b>Purpose</b>	<p>The Carle Foundation encourages activities that foster and enhance the quality of clinical research and patient care. At the same time, The Carle Foundation seeks to ensure that personal financial interests do not create a conflict of interest that improperly influences the exercise of researchers' professional duties. The Carle Foundation has implemented this policy to:</p> <ol style="list-style-type: none"> <li>1. Require all Investigators and other Key Research Personnel (as defined below) as well as their spouses and dependent children to disclose financial interests that may present a conflict of interest.</li> <li>2. Establish an institutional process to identify and review such disclosures, and to manage, reduce or eliminate any conflicts of interest.</li> </ol>				

### Statement of Policy

1. **Purpose of Disclosure:** The existence of a significant financial interest or a conflict of interest does not indicate a lack of moral integrity. A disclosed financial interest that is deemed a conflict is merely a situation that must be evaluated and, if feasible, managed jointly by the Investigator and The Carle Foundation. However, an undisclosed significant financial interest cannot be properly addressed and carries with it the potential for sanctions.
2. **Disclosure Requirement:** This policy established a self-reporting process. It is the responsibility of each Investigator and other Key Research Personnel to determine whether he/she has a financial interest that would reasonably appear to be affected by the proposed research or educational activities and to correctly disclose it in a timely manner. Failure to report a significant financial interest, refusal to cooperate in the management of a conflict of interest or furnishing false, misleading or incomplete information may constitute professional misconduct and could be cause for disciplinary action.
3. **Review of Disclosures:** Completion of The Carle Foundation Research Financial Interest Disclosure Statement ("Disclosure Statement," see Attachment A) will initiate a review to determine whether a conflict of interest exists. The Research Integrity Officer is responsible for initial review of each Disclosure Statement. If a conflict of interest appears to exist, the Research Integrity Officer will review the potential conflict issue with the Vice President of Research and Chief Academic Officer and Institutional Official for a determination of any conditions or restrictions, if any, that should be imposed to manage, reduce or eliminate the conflict of interest.
4. **Confidentiality:** The Carle Foundation will protect the confidentiality of private investments and personal finances and will request information related only to financial relationships that might influence the objectivity of the research being conducted or the intellectual property being created. The Carle Foundation respects the privacy of its Investigators and Key Research Personnel and does not wish them to disclose financial or personal information that does not relate to a research project.
5. **Whistleblowers:** Third parties may report alleged conflicts of interest to the Research Integrity Officer. Reports by a third party will be held in confidence by the Research Integrity Officer to the extent possible but must include appropriate and adequate information in order to be investigated.
6. **Publications and Informed Consent:** Whenever there is an appearance of a conflict of interest, the relevant patient informed consent and all publications should contain a statement disclosing support received from, or financial interests in, any source outside of The Carle Foundation.
7. **Access to Information:** Upon proper request by the U.S. Department of Health and Human Services (HHS), The Carle Foundation will make information available to HHS regarding all conflicting interests identified and managed, reduced or eliminated pursuant to 42 CFR. Part 50, Subpart F.

### Definitions

**Conflict of Interest** – Situations in which financial or other personal considerations, may compromise, or have the appearance of compromising, an Investigator or other Key Research Personnel's professional judgment in designing, conducting, interpreting or reporting research.

**Conflict of Interest Disclosure Statement ("Disclosure Statement")** – The document that is used by The Carle Foundation to elicit information regarding conflicts of interest, potential conflicts of interest, significant financial interests and potential significant financial interests of Key Research Personnel. The Vice President of Research and Chief Academic Officer or his/her designee shall determine the content of the Disclosure Statement.

**Institutional Official** – The individual designated as the Signatory Official on the Federalwide Assurance on file with the Office for Human Research Protections or his/her designee.

## Definitions (cont.)

**Investigator** – Means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

**Key Research Personnel** – Investigators and other individuals who contribute to the scientific development or execution of a research study or research project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. These individuals participate in the conduct, reporting, supervision and management of human subjects' research.

**Research** – A systematic investigation, inquiry, or analysis designed to develop or contribute to generalized knowledge that will primarily benefit those beyond the study participants. Research includes activities that aim to test a hypothesis, discover or collate facts, principles, or effects, reach new conclusions, or reexamine information by the critical study of a subject or by a course of scientific inquiry. Research also encompasses basic and applied product development, activities for which research funding is available from a Public Health Services component through a grant or cooperative arrangement, as well as any experiment that involves a test article and one or more human subjects.

**Significant Financial Interest** – Anything of monetary value, including but not limited to, salary or other payments or compensation for services (e.g., consulting fees or honoraria, equipment, retainers etc.), equity interests (e.g., stocks, stock options or other ownership interests), property rights (e.g., patents, copyrights and royalties from such rights). Significant financial interest **does not** include:

1. Salary, royalties or other remunerations from The Carle Foundation; **or**
2. Income from seminars, lectures or teaching engagements sponsored by public or nonprofit entities; **or**
3. Income from service on an advisory committee or review panels for public or nonprofit entities; **or**
4. An ownership or equity interest for any one enterprise or entity that, when aggregated for the Key Research Personnel and the Key Research Personnel's immediate family (including spouse, The Carle Foundation-qualified domestic partner and dependent children), meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and; does not represent more than five (5) percent ownership interest in any single entity; **or**
5. Salary, royalties or other payments that when aggregated for the Key Research Personnel and the Key Research Personnel's immediate family (including spouse, Foundation-qualified domestic partner and dependent children) over the next twelve (12) months, are not expected to exceed \$10,000 from a single source; **or**
6. Mutual, pension or other funds over which the Investigator does not exercise control.

## Procedure

1. **The Carle Foundation Disclosure Statement:** All Investigators and other Key Research Personnel must have on file a current Conflict of Interest Disclosure Statement. Investigators and other Key Research Personnel will be required to update the Disclosure Statement at least annually, and are required to update the Disclosure Statement on their own initiative at any time a new conflict of interest arises or a significant financial interest is obtained.
2. **Contents of Disclosure Statements:** The Investigator and other Key Research Personnel must disclose any known or potential conflicts of interest and any significant financial interests that would reasonably appear to be affected by the proposed research or education activities. Disclosure is required only for current or potential, but not past, conflicts of interest or significant financial interests.
3. **Disclosure Updates:** If the Investigator or other Key Research Personnel obtain any new significant financial interests or if any new conflict of interest arises during the term of any research project, then the Investigator or other Key Research Personnel must complete a new Disclosure Statement and submit it to the Research Integrity Officer within ten (10) business days of the date that the new significant financial interest is acquired or the new conflict of interest arises.
4. **Conflict of Interest Determination:** The Research Integrity Officer, in consultation with the Director of Compliance, will promptly review all Disclosure Statements received and will review the potential conflict issue with the Vice President of Research and Chief Academic Officer and Institutional Official for a determination of any conditions or restrictions, if any, that should be imposed to manage, reduce or eliminate the conflict of interest.  
The following determinations are available:
  - a. Permitted as is because the disclosed conflict or financial interest is minimal and does not represent a possible source of unreasonable bias or an inappropriate activity; **or**
  - b. Permitted with implementation of one or more conditions to preclude unreasonable levels of bias or inappropriate activities, with appropriate follow-up and review; **or**
  - c. Unacceptable and prohibited.
5. **Conflict Management Options:** Possible conflict management options include, but are not limited to:
  - a. Public disclosure of all relevant information.
  - b. Reformulation of the research project.

**Procedure (cont.)**

- c. Close monitoring of the research project by independent reviewers.
  - d. Divestiture of relevant significant financial interests.
  - e. Termination or reduction of involvement in the relevant research project.
  - f. Severance of outside relationships that pose conflicts.
  - g. Implementation of measures and protective factors in the design of the study to minimize potential bias, such as multiple investigators, blinding, or objective endpoints.
6. **Reporting to Sponsor:**
- a. Prior to the expenditure of any research funds where it has been determined that a conflict of interest does exist, The Carle Foundation will assure that the interest has been managed, reduced or eliminated in accordance with federal regulations and this Policy. If for any reason The Carle Foundation finds that it is unable to satisfactorily manage a conflict of interest, the Institutional Official or his designee will promptly notify any federal funding agency or sponsor related to the research project.
  - b. If The Carle Foundation determines, through enforcement of its policy on research misconduct, that an Investigator has biased the research, the Institutional Official or his designee will promptly notify the research sponsor of the corrective action taken or to be taken.
7. **Monitoring:** The Research Integrity Officer in conjunction with the Vice President for Research and Chief Academic Officer is responsible for monitoring the Investigator's compliance with any conflict management plan implemented.
8. **Sanctions:**
- a. Possible sanctions for violation of this policy, including but not limited to refusal to submit the required Disclosure Statement; furnishing false, misleading or incomplete information on the Disclosure Statement; or failure to comply with decisions rendered under this policy, can range from administrative intervention to termination, all in accordance with applicable Carle Foundation policies and bylaws.
  - b. Violations of this policy that appear to have resulted in misrepresentation of research results or other unprofessional conduct will be handled according to The Carle Foundation's policy on research misconduct.
  - c. Violations of federal or state statutes and guidelines will be handled according to federal and state laws and requirements.
  - d. The Research Integrity Officer will document all decisions regarding conflicts.
  - e. Violations of this policy relating to participation in federally funded projects also shall be reported to the Awarding Component.
  - f. Any penalties imposed by an external funding agency shall be deemed separate from any imposed by The Carle Foundation.
9. **Records Retention:** The Compliance Department will retain records relating to actual conflicts of interests for three (3) years after the date of submission of the final expenditures report for the award to which they relate, or until the resolution of any agency action involving those records, whichever is later. All reasonable measures will be employed to protect the confidentiality of the records.
10. **Training:** Investigators and other Key Research Personnel will be required to participate in any related training required by The Carle Foundation.

**Attachment**

Attachment A: Research Financial Interest Disclosure Statement

**References**

- 42 CFR. Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought

**Electronic Approval on File**

Melissa Phillips, RN  
Director of Cancer Center

Anna Keck, PhD  
Executive Director of the Research Institute

Charles Sanders, MD  
Vice President of Research and Chief Academic Officer

R. Bruce Wellman, MD  
CEO of Carle Physician Group  
Institutional Official

**Policy 103 - Attachment A:  
THE CARLE FOUNDATION RESEARCH FINANCIAL INTEREST DISCLOSURE STATEMENT**

**Instructions:** This form is to be completed in connection with The Carle Foundation's Research Policy 103 – Conflicts of Interest in Research. If you are an Investigator or other Key Research Personnel involved in the design, analysis, conduct or reporting of the results of research that engage The Carle Foundation, you must disclose any significant financial interests and associations with an entity that might be affected by the research. Please remember that you also must disclose the financial interests of your spouse or qualified domestic partner and dependent children.

Your answers to the following questions do not necessarily mean that any financial interest you list is improper or impermissible.

Print Your Name: \_\_\_\_\_

Title: \_\_\_\_\_ Department: \_\_\_\_\_

**I certify by my signature below that the statements set forth in this document are true and correct and that I have made all reasonable efforts to furnish accurate and complete information.**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Signature**

Reason for Disclosure:

- Annual Submission
- Change in Significant Financial Interest

1. Do you have any equity interest (e.g., stocks, stock options, or other ownership interests) in any entity providing funds for your research?

**You:**  Yes  No      **Your Family:**  Yes  No

If yes, does the amount of equity interest equal 5% or more of the total assets of the entity or exceeds \$10,000 in value?  Yes  No

If yes, please describe: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2. Do you have any ownership interest in any entity that owns intellectual property (e.g. patents, copyrights, or royalties) that could reasonably appear to be affected by your research?

**You:**  Yes  No      **Your Family:**  Yes  No

If yes, please describe: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

3. Do you have an ownership interest in any entity that could reasonably appear to be affected by your research?

**You:**  Yes  No      **Your Family:**  Yes  No

If yes, please describe: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

4. Do you serve as an employee, a paid consultant, officer, administrator, board member or speaker for any entity that is providing funds for your research, that could reasonably appear to be affected by your research, or that has an interest in intellectual property that could reasonably appear to be affected by your research?

**You:**  Yes  No      **Your Family:**  Yes  No

If yes, please describe: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

5. Have you received in the last 12 months, or will you receive in the next 12 months, more than \$10,000 in cash or something of value from an entity that could reasonably appear to be affected by your research (other than your salary from The Carle Foundation)? To answer this question, you should add the amount you receive to the amount that family members receive.

**You:**  Yes  No      **Your Family:**  Yes  No

If yes, please describe: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

6. Is there anything not covered in this questionnaire that you believe might constitute a conflict of interest or create the appearance of a conflict of interest related to your research?

**You:**  Yes  No      **Your Family:**  Yes  No

If yes, please describe: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Review/Action:**

Date: \_\_\_\_\_ Name of the Reviewer \_\_\_\_\_

- No conflict of interest exists.
- Conflict of interest exists and approval of this research project is denied.
- Conflict of interest exists but it is minimal (less than \$10,000 per year or less than 5% equity ownership) and no management is recommended.
- Conflict of interest exists. Following conditions are imposed for management of the conflict: