Title	RES - Conflicts of Interest in Research				
Region	Carle Health Central - BroMenn, Carle Health Central - Eureka, Carle Health East, Carle Health South, Carle Health West - Methodist, Carle Health West - Pekin, Carle Health West - Proctor				
Scope	All Entities				
Document type	Policy & Procedure				
Owner	Kathy Dams (Dir - Grants Admin&Research Op)				
Reviewer(s)	Amada Guerra (Grants Business Accountant), Cassandra Paul (Sr Research Award Negotiator)				
Approver(s)	APM Administrators, Jennifer Eardley (VP, Research)				
Effective Date	09/01/2005	**Next Review Date**:	11/30/2025	**Approval Date**	11/30/2023

Attachments

A - Research Conflict of Interest Disclosure Statement for Carle Researchers
B - Research Conflict of Interest Disclosure Statement for Non-Carle Researchers

Purpose/Scope

A. To ensure that personal financial interests do not create a Conflict of Interest that improperly influences the exercise of Investigators' professional duties and to ensure the integrity of research performed at Carle.

Definitions

A. **Conflict of Interest –** Created when the institution as a whole or individual representative of the institution has or appears to have competing professional or personal obligations or personal or financial interests that would make it difficult for the institution or the individual(s) to fairly conduct and oversee a research project.

B. **Carle Research Conflict of Interest Disclosure Statement** – The **Research Conflict of Interest Disclosure Statement** - Issued by the Foundation to elicit information regarding Conflicts of Interest, potential Conflicts of Interest, significant financial interests and potential Significant Financial Interests of Key Research Personnel.

C. **Financial Conflict of Interest** – A Financial Conflict of Interest exists when the institution, through its designated official(s), reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct or reporting of institution research.

D. **Foundation** – Includes each affiliate, subsidiary and division of The Carle Foundation ("Carle").

E. **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.

F. **Institutional Responsibilities** – An Investigator's professional activities on behalf of his/her Institution which may include teaching, administration, research, professional practice, and institutional committee memberships.

G. **Investigator** – 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. [45 CFR 46.402, 21 CFR 50.3] When there may be more than one investigator at a site such as a Co-Investigator or Sub-Investigator, then an investigator should be designated as a Principal Investigator. However Co-Investigator(s) and Sub-Investigator(s) are key research personnel who have responsibilities similar to that of the Principal Investigator on a research project. While the Principal investigator has ultimate responsibility for the conduct of the research project, the Co-Investigator or Sub-Investigator is also obligated to ensure the project is conducted in compliance with applicable laws, regulations and policy governing research.
   1. **Co-Investigator** – An individual involved with the principal investigator in the scientific development or execution of the research study.
   2. **Sub-Investigator** – Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

H. **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 directly from the funding source. These individuals participate in the conduct, reporting, supervision and management of human subjects research.
   1. Individuals who have minor roles in the research are not required to be listed on the IRB application and are not required to complete the training requirements. However, the Principal Investigator is responsible for ensuring that these individuals receive adequate training in accordance with their roles in the research.

I. **Public Health Services (PHS)** – An operating division of the Department of Health and Human Services 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. References to PHS include organizational units within PHS that have delegated authority to award financial assistance to support scientific activities, *e.g.*, Bureaus, Institutes, Divisions, Centers or Offices.

J. **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 PHS component through a grant or cooperative arrangement, as well as any experiment that involves a test article and one or more human subjects.

K. **Research Conflict of Interest Committee** – An Institutional committee at Carle that reviews any potential Conflict of Interest in Research. At a minimum this committee includes the, VP of Research, Corporate Integrity Officer, and Research Integrity Officer.

L. **Significant Financial Interest** – A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

1. With regard to any publicly traded entity, a Significant Financial Interest exists if 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.), received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, equipment, paid authorship); equity interest includes anything of monetary value.
2. With regard to any non-publicly traded entity, a Significant Financial Interest
   a. exists if anything of monetary value is received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds $5,000; or
   b. when the Investigator (or the Investigator's spouse or dependent children) holds **any** equity interest.
3. With regard to intellectual property rights and interests that when aggregated exceeds $5,000.
4. In addition, when research is supported by PHS funding, any reimbursed or sponsored travel that is related to the Investigator's Institutional Responsibilities that have not been paid for by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education, must also be disclosed.
5. Significant Financial Interest **does not** include:
   a. Salary, royalties or other remunerations paid by the employing Institution;
   b. Income from seminars, lectures or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
   c. Income from service on an advisory committee or review panels for a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; **or**
   d. Income from investment vehicles such as mutual funds and retirement accounts or other funds over which the Investigator does not exercise control.

Statement of Policy

A. **Purpose of Disclosure:** 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 Carle. However, an undisclosed significant financial interest cannot be properly addressed and carries with it the potential for sanctions.

B. **Disclosure Requirement:** All Investigators must have on file a current COI Disclosure Statement. Investigators will be required to update the Disclosure Statement at least annually and within thirty (30) days after a new Significant Financial Interest is received or acquired (e.g. through purchase, marriage, or inheritance).

- Investigators who are also employees of Carle are to use the electronic Conflict of Interest Disclosure form found in Lawson. Employees who do not have access to the electronic form, are to use the A - Conflict of Interest Disclsoure Statement.
- Investigators who are not Carle employees are to complete B -The Conflict of Interest Disclosure Statement for Non-Carle Researcher .

Additional Requirements when Applying for PHS Funding

1. Prior to the submission of an application to the PHS agency for funding, Investigators must have an up to date disclosure of all Significant Financial Interests. Any new Investigator, who subsequent to the submission of an application to the PHS grantee or during the course of the research project, plans to participate in the project, must also disclose their Significant Financial Interests to the designated official at least annually during the period of the award. In addition, an updated disclosure of Significant Financial Interests must be updated within thirty (30) days of discovering or acquiring new Significant Financial Interests.
2. Each Investigator who is participating in research under a subaward where the prime award originates from PHS, must submit an updated disclosure of Significant Financial Interests.

C. **Review of Disclosures:** COI Statements with disclosures will be reviewed for potential conflicts. The Research Integrity Officer is responsible for review of the Disclosure Statements for research. As necessary, if a Conflict of Interest appears to exist, the Research Integrity Officer will review the potential conflict issue with the VP of Research and Corporate Integrity Officer for a determination of any conditions or restrictions, if any, that should be imposed to manage, reduce or eliminate the conflict of interest.

D. **Conflict Management Options:** Possible conflict management options include, but are not limited to:
1. Public disclosure of all relevant information;
2. For research involving human subjects, disclosure of Investigator financial interests directly to participants;
3. Modification of any Research proposal or plan;
4. Close monitoring of the research project by independent reviewers;
5. Divestiture of relevant significant financial interests;
6. Termination or reduction of involvement in the relevant research project;
7. Severance of outside relationships that pose conflicts; and/or
8. Implementation of measures and protective factors in the design of the study to minimize potential bias, such as multiple investigators, blinding, or objective endpoints.

E. **Reporting Disclosures:** No expenditure of sponsor funding for research shall occur with respect to any research project for which the committee has determined that a management plan is required until all reporting requirements have been met. For any Significant Financial Interest requiring disclosure that is identified after the funding for the research is awarded, it will be determined whether a management plan is required and for PHS awards, whether a Financial Conflict of Interest exists. Additionally, each award year, Carle must provide the PHS funding agency an annual Financial Conflict of Interest report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the project period. The annual FCOI report is due at the time of the progress report.

F. **Training:** Investigators are required to complete Conflict of Interest training at least every four (4) years prior to engaging in any PHS funded research, and immediately under the following circumstances:
1. when Carle's Conflict of Interest in Research policy changes in a manner that affects Investigator requirements;
2. when an Investigator is new to the institution; or
3. when an Investigator is not in compliance with this policy or management plan.

G. **Failure to Comply with this Policy:** The Investigator is ultimately responsible for making any necessary disclosures as required by this Policy and to follow any prescribed plan for the management, reduction, or elimination of an identified Conflict of Interest. Failure to do so shall be deemed a violation of this policy. PHS Investigators are also subject to the following procedures when financial conflict of interest is not identified or managed in a timely manner including: failure by the Investigator to disclose a Significant Financial Interest that is determined to constitute a Conflict of Interest; failure by Carle to review or manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a Financial Conflict of Interest management plan. The following actions need to take place:
1. A management plan must be implemented that shall specify the actions that have been, and will be taken to manage the Financial Conflict of Interest going forward;
2. Within 120 days of determination of noncompliance, Carle must complete a retrospective review of the Investigator's activities and the PHS funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of the research.
3. Following the completion of the retrospective review, the Financial Conflict of Interest report to PHS may be updated, and if bias is found, a mitigation report will be completed as well in accordance with PHS regulations.

H. **Application of this Policy to Subrecipients:** For PHS sponsored research that involves subcontractors, subgrantees or subawardees (collectively "Subrecipients") at other institutions, Carle requires a written agreement from Subrecipients that establishes whether Carle's policy or the subrecipient shall apply to the Subrecipient's Investigators. In all cases, Carle must report to the PHS funding agency any Subrecipient Financial Conflicts of Interest prior to the execution of the subcontract or within sixty (60) days of identification of a new Financial Conflict of Interest by the Subrecipient or Carle that arises during the term of the subcontract. If the Subrecipient's policy is used, the Subrecipient must certify that its Financial Conflict of Interest policy is compliant with 42 CFR Part 50 Subpart F and 45 CFR Part 94 and will be responsible for ensuring that the Subrecipient institution and its Investigators comply with the federal regulations. Subrecipients must report to Carle as the awardee institution, any identified Financial Conflict of Interest within ten (10) business days from the management plan agreement with the Subrecipient's Investigator, but no later than forty-five (45) days after identification of the Financial Conflict of Interest by the Subrecipient. If Carle's policy is used, the Subrecipient must ensure that its Investigators submit the Investigator's Disclosure Form to Carle for review.

I. **Public Accessibility:** The Institution will respond to a written request, within five (5) business days for information concerning any disclosed Significant Financial Interest that meets the following criteria:
   1. that it has been determined to be a financial conflict of interest; and
   2. that it has been determined to be related to PHS Funding.

   The written request is to be addressed to the Office of Corporate Compliance identifying which PHS funded study for which information is sought.

J. **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.

Procedure N/A

Other Related Links As Applicable To Site N/A

References

- 42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought.
- 45 CFR Part 94, Responsible Prospective Contractors.