

**The Carle Foundation
IRB Policy 106**

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| Subject | Conflict of Interest | | |
| Approval | Dec 2006 | Review | Sep 2010 |
| Revision | Jun 2009 | | |
| Scope | These policies apply to all IRB members and all investigators submitting research to the Carle IRB. | | |
| Purpose | To effectively eliminate or manage conflicts of interest in the conduct of research. | | |

Statement of Policy

1. Conflicts of interest ("COI") must be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

Specific Policies

1. Definition of an Investigator COI
 - a. A conflict of interest is any relationship which might reasonably influence an Investigator and Co-Investigator(s) to act other than in the best interest of the individuals participating in a research study, or could bias or improperly influence the conduct of the research, the Investigator's interpretation of data or his or her clinical or scientific judgment.
 - b. Examples of a conflict of interest include:
 - Receipt or promise of any item of value, including:
 - Promises of future employment;
 - Consulting agreement payments;
 - Honoraria;
 - Other items of value.
 - Equity interests in a Sponsor, or in an affiliate of a Sponsor;
 - Intellectual property rights, such as royalties, which are subject to or will vary based on the outcome of a study;
 - Payments related to promotion of a test article or approved drug sold by the Sponsor of a test article;
 - Payments over more than \$25,000 (other than fair market value compensation for services provided as part of the study) made by a Sponsor to the Investigator (or an entity or individual which supports or benefits the Investigator) to support activities of the Investigator, such as grants for ongoing research, equipment, or retainers, during the study and for one year following the completion of the study;
 - Selection of an Investigator by a Sponsor based on use of the Sponsor's drugs or devices;
 - Ownership of a material financial interest of 5% or more in the sponsoring company or holding a financial ownership interest which contributes materially to the Investigator's income; or
 - Other personal relationships, activities or interests which may impair an Investigator's objectivity or which may inappropriately influence an Investigator's decisions or actions relative to research
 - c. Consideration is given to COI of both the Investigator and the immediate family members of the Investigator (*i.e.*, the spouse, domestic partner, parent and dependent children of the Investigator).
2. Identification and Resolution of Investigator COIs
 - a. All potential conflicts of interest for each Investigator shall be disclosed to the IRB at the time of application for review of a study or, if the conflict of interest arises after consideration of the initial application, as soon as the potential conflict of interest is identified. The IRB shall consider the facts which relate to the conflict of interest and may impose such conditions or limitations as the IRB may consider appropriate to ensure the safety and ethical treatment of human subjects and the scientific validity of the research conducted, in accordance with Section 5.b below. The IRB may refer questions regarding COI to the Ethics Committee.
3. Definition of an Institutional COI
 - a. An institutional COI is defined as a relationship between CFH or an affiliate and a research Sponsor, where the outcome of a study may impact the financial value or relative relationship between the CFH and the Sponsor. Fair market value payment for services rendered, including a reasonable profit, by the Sponsor does not create an institutional COI. Technology transfer agreements or similar agreements between the Institution and a Sponsor may create the appearance of a COI, and thus approval and oversight of the research by the IRB shall be kept separate from the negotiation of intellectual property rights.

Specific Policies (cont.)

4. Evaluation of COIs

- a. Each Investigator shall provide to the IRB and to Sponsors and governmental agencies, as appropriate, accurate and complete information regarding potential COIs as requested or required by law, but in any case at least once annually.
- b. The Carle IRB will review COI reports as necessary to evaluate the COI and determine whether the COI should be resolved or managed. As necessary a legal consultant may be contacted and utilized.
- c. The evaluation will consider, at a minimum:
 - Risks to participants;
 - Procedures available for ensuring the scientific and scholarly integrity of the research;
 - Whether the COI will impact the selection of participants;
 - Any risk of coercion or undue influence during the consent process;
 - Information regarding the COI provided to participants;
 - Provisions for data monitoring/IRB oversight;
 - Privacy protections for participants;
 - The impact of the COI on the credibility of the research program as a whole.

5. Management of Investigator COI

- a. Disclosure
 - All investigators must disclose conflicts of interest (as defined by Carle Foundation Hospital SOPs) to the IRB. The IRB is also aware that there may be additional financial conflicts of interest that are not included in this definition. Investigators are required to disclose any other arrangements or relationships which might reasonably constitute a COI, including financial relationships with companies sponsoring research, such as consulting agreements.
- b. Management Options
 - The IRB will review each COI on a case-by-case basis using the above criteria. The IRB may require:
 - That conflicts be disclosed in the informed consent;
 - That the Investigator recuse him/herself as an Investigator, or refrain from participating in the study entirely;
 - That significant financial interests be publicly disclosed;
 - That the study be monitored by independent reviewers;
 - Modification of the research plan;
 - Divestiture of significant financial interests;
 - Severance of relationships that create actual or potential conflicts;
 - More frequent review of the project by the IRB;
 - Public disclosure of any COI, including disclosures at any presentation or publication of research data;
 - Any other action reasonably expected to protect human subjects from any consequences of the COI.
- c. Goal of COI Management
 - The means used to manage an Investigator COI will be calculated to, as a primary result, protect human participants, and to preserve the reputation of the research program as a whole.
- d. COIs That May Adversely Affect Participant Protection
 - In no event will disclosure of the COI on the consent form be the sole means of managing a COI that the IRB reasonably believes may adversely affect participant protection.

6. Management of Institutional COI

- a. Identification of Institutional COI
 - The IRB will work with the Institutional Official to identify the existence of any Institutional COI
- b. Management of Institutional COI
 - When a potential Institutional COI has been identified, it will be managed by:
 - Isolating decision-making for issues related to the institutional COI from decision-making for human subject protections.
 - Ensuring that full disclosure of all study results is required in any study.
 - Other reasonable measures identified as useful by the Ethics Committee.

Specific Policies (cont.)

7. Disclosure and Documentation of Financial Interest and COI of IRB Members

- a. No regular or alternate IRB member may participate in the initial or continuing review of any research project in which the member has a conflict of interest, except to provide information as requested. An IRB member is deemed to have a COI when the IRB member is participating in the research in any manner, or when the outcome of the research will materially impact (favorably or unfavorably) the IRB member financially or professionally. An IRB Member shall consider himself the subject of a COI if the IRB Member, due to personal reasons, is unable to evaluate a study from the perspective of protecting human subjects. It is the responsibility of each voting member or alternate member of the IRB to disclose any COI affecting a study submitted to IRB and recuse him or herself from all deliberations and voting related to that study. The procedures for recusal of IRB members, including the Chairperson, from deliberating/voting on all protocols for which there is a potential, actual financial, or other conflicts of interest are detailed in [IRB Functions and Operations Policy 302 IRB Meeting Administration](#).

8. Employees

- a. Institutional staff whose job status or compensation is or might be affected by research that is reviewed by IRB must recuse themselves from any meeting at which such a protocol is reviewed. If an employee is a member of the IRB, the IRB Member COI provisions apply.

9. Education and Training in COI

- a. IRB members and staff are required to participate in education and training activities related to financial conflict of interest issues, as set forth in the Training and Education Policy and as otherwise required by CFH.

10. Sanctions

a. Carle Employees

- Failure of Carle employees to comply with this policy, whether due to failure to report potential COIs or refusal to comply with management processes as approved by the Carle IRB, will be grounds for disciplinary action in accordance with the policies of CFH.

b. Investigators

- Failure of Investigators to comply with this policy, whether due to failure to report potential COIs or refusal to comply with management processes as approved by the Carle IRB, will be grounds for discipline including, as appropriate, termination of approval for the research project, or termination of the Investigator as an approved Investigator at Carle.

c. IRB Members

- Failure of any IRB Member to report COIs, or to appropriately recuse themselves from consideration of any research project, with which a COI exists, may result in such sanctions as the IRB Chairperson, in consultation with the Institutional Official, may determine.

d. Reports

- As required or appropriate, the Carle IRB shall report issues related to COI or failure to comply with management requirements to the CFH governing body, OHRP, FDA or any other appropriate governmental entity.

Reference

45 CFR 46 and Carle IRB Policies

Approval On File

*Approved by IRB Board Aug 2010

Kyle Galbraith, PhD
Interim Manager of Human Subject Protection

Anna Keck, PhD
Executive Director of the Research Institute

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

Carle IRB Contact:
Carle Foundation Hospital
Carle Institutional Review Board
611 West Park Street
Broadway Research Center (BWRC)
Urbana, IL 61801
Phone: 217-383-4366
Fax: 217-383-3993
Email: irb@carle.com

Web: www.carleconnect.com/irb.shtml

