

Driscoll Health System

Chapter 1: Administration	Subchapter 1.6: IRB/Research	Effective Date: 12/17/14
Title: Conflict of Interest in Research		

- Driscoll Health System Department _____ Driscoll Health Plan
 Driscoll Children's Hospital Physician Groups

PURPOSE:

To promote objectivity in research by enabling affected individuals to understand identify, manage and appropriately disclose actual, potential or perceived conflicts of interest, including financial conflicts of interest.

PERSONS AFFECTED:

Any person regardless of title or position, who is responsible for the design, conduct, or reporting of research, including researchers, investigators and key personnel (or their spouse and dependent children) on behalf of Driscoll Children's Hospital (collectively referred to in this policy as "Investigator").

DEFINITIONS:

Conflict of Interest: a situation in which an interest may compromise, or have the appearance of compromising, an Investigator's professional judgment in conducting research or that conflicts with an obligation to uphold another party's interest, thereby compromising objectivity and impartiality. A conflict of interest includes, but is not limited to, a significant financial interest.

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:

- With regard to any publicly traded entity, when the value of any remuneration (salary and any payment for services not otherwise identified as salary, for example consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding disclosure of the interest aggregated with the value of any equity in the entity (for example, stock, stock options, or other ownership interests as determined through reference to public prices or other reasonable measures of fair market value) as of the date of the disclosure exceeds \$5,000;
- With regard to any non-publicly traded entity, when the aggregated value of any remuneration received from the entity in the twelve (12) months preceding disclosure of the interest exceeds \$5,000 or any equity in the entity; or , when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
- Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.

- The term Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Hospital to a person if the person is currently employed or otherwise appointed by the Hospital, including intellectual property rights assigned to the Hospital and agreements to share in royalties related to such rights; income from seminars, lectures, or teaching engagements or service on advisory committees or review panels sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Public Health Service (PHS): means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which authority involved may be delegated, including the National Institutes of Health (NIH) and the Agency of Healthcare Research and Quality.

POLICY:

It is the policy of Driscoll Children’s Hospital (DCH) to ensure that research activities are free from bias resulting from conflicts of interest.

PROCEDURE:

1. Each protocol submitted to the IRB for review must be accompanied by a Disclosure of Conflict of Interest Form for each Investigator involved in the covered study.
 - a. The Disclosure of Conflict of Interest Form must be completed, signed and submitted with each Initial and Continuing Application for Review.
 - b. Within 30 days of discovering or acquiring a new conflict of interest the affected individuals must review this policy, file an updated Disclosure of Conflict of Interest Form, and forward it to the DCH Institutional Review Board (IRB).
 - c. The responsibility to report such actual or potential conflict rests with the affected individual. Failure to comply with this policy may result in disciplinary action and/or the denial of the right to participate in research at DCH.
2. Prior to commencement of research activities, the IRB will review the Disclosure of Conflict of Interest Form to determine whether a conflict of interest exists.
 - a. Neither the sponsor, nor the Investigator, or any individual involved in the conduct of the research activity under review will participate in the IRB review or conclusions except to provide information upon request.
3. If a conflict of interest is identified, the IRB may issue a management plan to manage the conflict of interest. Management plans may include, but are not limited to:
 - a. public disclosure of the conflict of interest;
 - b. disclosure of conflicts of interest directly to human subject research participants;
 - c. appointment of a research monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the conflict of interest;
 - d. modification of the research plan;
 - e. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

- f. reduction or elimination of the conflict of interest (e.g., sale of an equity interest); or
 - g. severance of the relationship(s) that create financial conflicts.
4. Identified conflict of interests for all Public Health Service (PHS) funded studies must be addressed and reduced, eliminated, and managed prior to spending any project funds.
 5. Conflicts of Interest for Investigators who are working on PHS funded projects will be disclosed, upon request, to any member of the public. The information provided upon request will include: Investigator's name, Investigator's title and role with respect to the research project, the name of the entity in which the FCOI is held, the nature of the FCOI, and the approximate dollar value of the FCOI. DCH will respond within 5 business days of a request. Requests must include the Investigator's name and the name of the PHS funded research and be mailed to:
 - Institutional Review Board
 - Driscoll Children's Hospital
 - 3533 S. Alameda St.
 - Corpus Christi, TX 78411
 6. If an Investigator fails to comply with this policy or a related management plan, and the non-compliance appears to have biased the design, conduct, or reporting of the PHS-funded research, DCH shall promptly notify the PHS awarding agency of the corrective action taken.
 7. This policy is to be published on the DCH public website.

REFERENCES:

- 42 Code of Federal Regulations Part 50 Subpart F
- 45 Code of Federal Regulations Part 94



DRISCOLL CHILDREN'S HOSPITAL CONFLICT OF INTEREST DISCLOSURE FORM

This form is required to be completed prior to the commencement of research activities at Driscoll Children's Hospital. Institutional review of research projects will be pending receipt of this disclosure from all involved personnel as set forth in the Conflict of Interest in Research policy.

SECTION I. Researcher Information

Name _____	Department _____
Email _____	Phone _____ FAX _____
Do you participate in Public Health Service (PHS) funded research? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Role in Research at Driscoll: _____	

SECTION II. Significant Financial Interests Disclosure

In the 12 months preceding this disclosure, have you or your family members had a Significant Financial Interest (SFI) in ANY (choose yes or no for each question):

Yes	No	
		Publicly Traded Entity in which your combined equity value (ownership of stock, options, etc.) AND income (in any one entity) exceeded \$5,000 and that entity appears to be related to your institutional responsibilities;
		Non-Publicly Traded Entity in which you had ANY ownership interest OR income exceeding \$5,000 (from any one entity), and that entity appears to be related to your institutional responsibilities;
		Intellectual Property from which you received ANY income, and the intellectual property appears to be related to your institutional responsibilities;
Or received:		
		Sponsored Travel \$5,000 or more that is paid for, or reimbursed directly to you, by any organization OTHER THAN an accredited, U.S. institution of higher education or by any U.S. government agency (federal, state, or local) and the sponsoring organization appears to be related to your institutional responsibilities;
Or held:		
		A Paid Position of Influence in which you had any authoritative or direction-shaping role in any entity NOT affiliated with DHS (including non-profit organizations) and the interests of the entity appear to be related to your institutional responsibilities.

If you checked 'Yes' to any of the above, complete Section III and sign Section IV.

If you checked 'No' to all of the above, sign Section IV.



DRISCOLL CHILDREN'S HOSPITAL
CONFLICT OF INTEREST DISCLOSURE FORM

SECTION III. Project-specific Significant Financial Interest disclosure for investigators with known significant financial interests. Complete a separate form for each outside company/entity.

Company or Entity Name _____

Company or Entity Type _____

Yes	No	
		<p>Have you or your family held any position or served on an advisory board of directors for this entity?</p> <p>Position Title: _____</p> <p>Held By: _____ Paid Amount: _____</p> <p>Please describe the roles and responsibilities of this position and relationship to your research project(s):</p>
		<p>Have you or your family owned assets in this entity? Percent Ownership _____</p> <p>Asset Type: _____</p> <p>Assets Owned By: _____ Current Value: _____</p> <p>Comments/Description. Describe any relationship to research project(s):</p>
		<p>Have you or your family received income from this entity?</p> <p>Income Type: _____</p> <p>Income Received By: _____ Annual Amount _____</p> <p>Describe the source of income, position or services for which it was received, and how it was related to your research project(s):</p>



**DRISCOLL CHILDREN'S HOSPITAL
CONFLICT OF INTEREST DISCLOSURE FORM**

Yes	No	
		<p>Have you or your family received any received any reimbursed/sponsored travel related to your institutional responsibilities? Travel Type: _____</p> <p>Travel Provided For: _____ Estimated Value: _____ Comments/Description: Please describe any relationship to your research project(s):</p>
		<p>Have you or your family received income related to intellectual property rights and interests? Intellectual Property Type: _____</p> <p>Assets Owned By: _____ Annual Amount: _____</p> <p>Comments/Description. Please describe the intellectual property and how/if it is related to your research project(s):</p>

SECTION IV. I certify that:

- I have reviewed the **Conflict of Interest in Research** policy and understand my obligations.
- The information submitted within this form is true, complete and accurate to the best of my knowledge.
- Any false, fictitious, or fraudulent statements may subject me to disciplinary action or criminal, civil, or administrative penalties.

Signature _____