

Driscoll Health System

Chapter: Administration	Subchapter IRB/Research	Effective Date: 06/05/2020
Title: Conflicts of Interest in Research		

- Driscoll Health System (DHS) Department: _____ Driscoll Health Plan (DHP)
 Driscoll Children's Hospital (DCH) 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 (FCOI).

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 Family Members) on behalf of Driscoll (collectively referred to in this policy as "Investigator").

DEFINITIONS/RELATED INFORMATION:

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.

Equity Interest: Any financial interest in the profits of, or stock of, a commercial or non-profit enterprise, a stock option, or any other ownership interest in a commercial or non-profit enterprise.

Family Member: An Investigator's spouse, domestic partner or dependent children.

Financial Interest: Anything of economic or monetary value, whether or not the value is readily ascertainable, possessed by the Investigator.

Institution of Higher Education: An educational institution in any state in the U.S. that meets all the following requirements:

- Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, or persons who meet the related requirements of federal law;
- Is legally authorized within such state to provide a program of education beyond secondary education;
- Provides an educational program for which the institution awards a bachelor's degree or provides not less than a two-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the U.S. Secretary of Education;
- Is a public or other nonprofit institution; and
- Is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted pre-accreditation status by such an agency or association that has been recognized by the U.S. Secretary of Education for the granting of pre-accreditation status, and the U.S. Secretary of Education has determined that there is

satisfactory assurance that the institution shall meet the accreditation standards of such an agency or association within a reasonable time.

Management Plan: A written plan to address a conflict of interest to ensure, to the extent possible, that the design, conduct and reporting of research shall be free from bias.

Public Health Service (PHS): The PHS of the U.S. Department of Health and Human Services and any PHS awarding components to which authority may be delegated, including without limitation the National Institutes of Health.

Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g. a published article, book or book chapter) and product development (e.g. a diagnostic test or drug) and includes any activity for which PHS research funding is available.

Significant Financial Interest: A financial interest consisting of one (1) or more of the following interests of the Investigator 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 (i.e., stock, stock option, or other ownership interest).
- Intellectual property rights and interests (i.e., patents, copyrights) upon receipt of income related to such rights and interests.
- The occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available); provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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.
- 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.

PROCEDURE:

1. **Investigator Training:** Investigators shall complete conflict of interest training, as coordinated through the IRB, at least every four (4) years, and immediately when any of the following circumstances apply:
 - a. Driscoll's conflict of interest policies and procedures have been revised in a manner that affects the Investigator;
 - b. an Investigator is new to Driscoll;
 - c. if the Investigator is not in compliance with this policy or the management plan; or
 - d. as otherwise directed by the FCOI Official.

2. The Investigator shall complete the *Disclosure of Conflict of Interest Form – Attachment A* and submit it along with the *IRB Submission Packet*.
 - a. *Attachment A* must be completed, signed and submitted annually thereafter with each continuing review or status review.
 - b. Within 30 days of discovering or acquiring a new actual or potential conflict of interest the affected individuals must review this policy and file an updated *Attachment A*.
 - 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 Driscoll.

3. Prior to commencement of research activities, the FCOI Official shall review the *Attachment A* to determine whether a conflict of interest exists. In making the determination, the FCOI Official may review the following (but it is not limited to):
 - a. the nature of the conflict;
 - b. the relatedness of the conflict to the research;
 - c. the perceived risk to the integrity of the research as a result of the conflict;
 - d. the specific risks to human subjects (if applicable);
 - e. the perceived risk to Driscoll's reputation; and
 - f. whether or not the conflict can be sufficiently managed by implementing a management plan.

4. Neither the sponsor, nor the Investigator, or any individual involved in the conduct of the research activity under review shall participate in the review or conclusions except to provide information upon request.

5. **Management Plan:**
 - a. If a conflict of interest is identified, the FCOI Official may issue a management plan to manage the conflict of interest. The management plan may include, but is not limited to:
 - public disclosure of the conflict of interest;
 - disclosure of conflicts of interest directly to human subject research participants;
 - 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;
 - modification of the research plan;
 - change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

- reduction or elimination of the conflict of interest (e.g., sale of an equity interest); or
 - severance of the relationship(s) that create financial conflicts.
- b. In developing the management plan, the FCOI Official may conduct factual inquiries and consult with the appropriate Driscoll Administrators.
 - c. The FCOI Official shall provide a copy of the management plan to the Investigator and the Institutional Review Board (IRB).
 - d. Management Plan Monitoring: The FCOI Official, or designee, shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the research project.
6. Identified conflict of interests for all PHS-funded research must be addressed and reduced, eliminated, and managed prior to spending any project funds.
 7. Conflicts of interest for Investigators who are working on PHS-funded projects shall be disclosed, upon request, to any member of the public. The information provided upon request shall 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. Driscoll shall respond within five (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:

FCOI Official
Driscoll Children's Hospital
3533 S. Alameda St.
Corpus Christi, TX 78411

8. 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, Driscoll shall promptly notify the PHS awarding agency of the corrective action taken.
9. This policy is to be published on the Driscoll public website.

INTERNAL REFERENCES:

IRB Submission Packet (located in the IRB office)
Conflict of Interest Disclosure Form – Attachment A

REFERENCES:

42 C.F.R., Part 50, Subpart F (Promoting Objectivity in Research)
45 C.F.R., Part 94 (Responsible Prospective Contractors)



CONFLICT OF INTEREST (COI) DISCLOSURE FORM

Please complete this form, regardless of title or position, if you are responsible for the design, conduct or reporting of research. This may include principal investigators (PI), collaborators and consultants.

DATE:

TO: FINANCIAL CONFLICT OF INTEREST (FCOI) OFFICIAL

FROM:

ROLE IN RESEARCH:

IRB OF RECORD:

DCH IRB NUMBER:

SPONSOR NUMBER:

STUDY TITLE:

SPONSOR:

DRISCOLL STUDY LOCATION, CONTACT INFORMATION (DEPARTMENT, COORDINATING CENTER):

SECTION I. COI, Study Information

This disclosure is an (choose one):	<input type="checkbox"/> Initial Disclosure for a research study. <input type="checkbox"/> Update to existing disclosure for an ongoing, existing research study (change in Significant Financial Interest (SFI), newly acquired SFI). <input type="checkbox"/> Annual update to an existing disclosure with changes (change in SFI, newly acquired SFI). <input type="checkbox"/> Annual Update to an existing disclosure with no changes. Sign and submit
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Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Does this research involve human subject research?
<input type="checkbox"/>	<input type="checkbox"/>	Does this study involve <u>chart review only</u> with no interaction or intervention?
<input type="checkbox"/>	<input type="checkbox"/>	Is this Public Health Service (PHS) funded research?
<input type="checkbox"/>	<input type="checkbox"/>	Is this study funded (sponsored) or managed by an external IRB?
<input type="checkbox"/>	<input type="checkbox"/>	Is COI Training current

Section II. Significant Financial Interests Disclosure

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

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Publicly Traded Entity in which your combined equity value (ownership of stock, options, etc.) AND income (in any one entity) exceeded \$5000 and that entity appears to be related to your institutional responsibilities;
<input type="checkbox"/>	<input type="checkbox"/>	Non-Publicly Traded Entity in which you had ANY ownership interest OR income exceeding \$5000 (from any one entity), and that entity appears to be related to your institutional responsibilities;
<input type="checkbox"/>	<input type="checkbox"/>	Intellectual Property from which you received ANY income, and the intellectual property appears to be related to your institutional responsibilities;
Or received:		
<input type="checkbox"/>	<input type="checkbox"/>	Sponsored Travel \$5000 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:		
<input type="checkbox"/>	<input type="checkbox"/>	A Paid Position of Influence in which you had any authoritative or direction-shaping role in any entity NOT affiliated with Driscoll (including non-profit organizations) and the interests of the entity appear to be related to your institutional responsibilities.

Section III. Project-specific Significant Financial Interest (SFI) for which disclosure of interest would be required according to the definition in the "Conflicts of Interest in Research Policy". If you answered "Yes" to any of the questions on Section II and III, please provide the name of the company or entity with whom the financial arrangement exist. If there is no known company or entity, please check N/A below. If more than one company/entity, copy the section to add outside company/entity.

Company or Entity Name	
Or N/A <input type="checkbox"/>	

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Have your family held any position or served as advisory board of directors for this entity?
		Position Title:

			<p>Held by:</p> <p>Paid Amount:</p> <p>Please describe the roles and responsibilities of this position and relationship to your research study:</p>
Yes <input type="checkbox"/>	No <input type="checkbox"/>		<p>Have you or your family owned assets in this entity?</p>
			<p>Percent Ownership:</p> <p>Asset Type:</p> <p>Assets Owned By:</p> <p>Current Value:</p> <p>Comments/Description. Describe any relationship to research study:</p>
Yes <input type="checkbox"/>	No <input type="checkbox"/>		<p>Have you or your family received income from this entity?</p>
			<p>Income Type:</p> <p>Income Received By:</p> <p>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 study:</p>
Yes <input type="checkbox"/>	No <input type="checkbox"/>		<p>Have you or your family received any reimbursement/sponsored travel related to your institutional responsibilities?</p>
			<p>Purpose of Travel:</p> <p>Travel provided By:</p> <p>Estimated Value:</p> <p>Date(s) of Travel:</p> <p>Comments/Description: Please describe any</p>

			relationship to your research study?
Yes <input type="checkbox"/>	No <input type="checkbox"/>		Have you or your family received income related to intellectual property rights and interests?
			Assets Owned By: Annual Amount: Comments/Description: Please describe the intellectual property and how/if it is related to your research project?

Section IV. I certify that:

<ul style="list-style-type: none"> • 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. <p>Signature: _____ Date: _____</p>
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