

Policy Number: RES 4.0
Policy Title: Conflict of Interest in Research
Chapter Location: Research

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Policy Statement: This document establishes standards 1) for required training related to conflict of interest in research, 2) for disclosure of potential conflicts as they may apply to research, and 3) for methods to manage and/or eliminate potential conflicts of interest.

Purpose: Gillette Children's mission is "In collaboration with patients, families and partners, we redefine what is possible for children with brain, bone and movement conditions through clinical leadership, research and global advocacy." Gillette's Research Program supports this mission. In order to redefine what is possible for children with brain, bone and movement conditions, Gillette researchers form relationships with collaborators from other institutions, as well as with partners in the medical community, industry, government, and other external entities. To maintain the public trust, to protect the integrity of professional judgment, and to ensure appropriate stewardship of resources and compliance with applicable state and federal laws, it is important that external relationships not be, or appear to be, influenced by factors other than the best interests of the patient, the pursuit of knowledge, and the appropriate stewardship of resources. Specifically, in the case of research, a conflict may arise when a Gillette researcher compromises professional judgment in carrying out research, teaching, outreach, or public service activities because of an external relationship that directly or indirectly affects the financial or business interest of the Gillette researcher, an immediate family member, or an associated entity (see definitions below). As such, external relationships that may cause conflicts of interest related to research must be proactively identified, managed, and monitored both annually as well as on an ongoing basis when new research projects are undertaken.

This policy establishes standards for required training related to conflict of interest in research, for disclosure of potential conflicts, and for methods to manage potential conflicts. Such management and oversight will promote transparency in research by eliminating or minimizing any bias resulting from an investigator's conflict of interest. This policy intends to balance the important medical and public benefit that external relationships can produce with the possibility that these relationships may cause a conflict of interest or the perception of a conflict of interest.

Scope: This policy applies to Gillette researchers, as well as any other Gillette employees, visiting researchers, or other outside collaborators affiliated with Gillette who are responsible for, or in a position to influence the design, conduct, or reporting of research or other scholarly activity.

Oversight: Research Governance Committee; Compliance and Privacy Counsel

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Definitions:

- **Associated Entity** - Any business over which an investigator, alone or together with an immediate family member, possesses a business or financial interest that would be required to be disclosed under this policy.
- **Business** - Any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust or any other nongovernmental legal entity organized for profit, nonprofit or charitable purposes, and which engages or attempts to engage with Gillette or the investigator.
- **Business Interest** - Holding any position, such as an employee, officer or director on a board, including an advisory board, regardless of compensation.
- **Compensation Relationship** - Includes, but is not limited to, the receipt or expectation to receive any remuneration such as consulting fees, honoraria, salary, rent, royalties or other such compensation, and that excludes compensation from Gillette.
- **Conflict of Interest** - May occur when there is a divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, and not on the character or actions of the individual.
- **Disclose or Disclosure** - The act or process of making information available to a third party such as a patient, researcher, or other relevant audience regarding the existence of a conflict of interest.
- **Financial Interest** - Ownership or investment interest in a business and/or a compensation relationship with a business.
- **Immediate Family** – An individual's spouse or domestic partner, dependents, and any other related person that may benefit from an individual's actions on behalf of Gillette.
- **Investigator or Researcher** - Any Gillette employee or non-employed person conducting or participating in research, in whole or in part, at a Gillette facility or using Gillette non-public information, patients or resources for purposes of research. An investigator is involved in a substantive and meaningful way in the design, conduct, or reporting of both funded and unfunded research at Gillette.
- **Non-financial Relationship** - Relationships with industry of a non-financial or non-business nature such as family or friendships with individuals employed by a business or industry, or non-compensated roles with an industry.
- **Ownership or Investment Interest** - Includes, but is not limited to, stock, stock options, debt interests or other ownership or investment rights, and excludes diversified mutual funds, pension funds or other institutional investments funds where the individual does not exercise control over the investments.
- **Participate** - To be a part of the described activity in any capacity including, but not limited to, serving as the principal investigator, co-investigator, research collaborator, or provider of

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direct services or patient care or having authority over any of the above. The term does not apply to the study participants, unless they are in a position to influence the study's results or have privileged information as to the outcome.

- **Reporting** - The act or process of making information available to Gillette regarding a potential conflict of interest.
- **U.S. Public Health Service (PHS) Agencies** include but are not limited to:
 - Agency for Healthcare Research and Quality (AHRQ)
 - Agency for Toxic Substances and Disease Registry (ATSDR)
 - Centers for Disease Control and Prevention (CDC)
 - Food and Drug Administration (FDA)
 - Health Resources and Services Administration (HRSA)
 - Indian Health Services (IHS)
 - National Institutes of Health (NIH), including all Centers and Institutes
 - Substance Abuse and Mental Health Services Administration (SAMHSA)

Policy: Gillette researchers responsible for, or in a position to influence, the design, conduct or reporting of research or other scholarly activity must comply with all applicable state and federal laws and regulations, including those related to conflict of interest and objectivity in research. These laws include, but are not limited to, Federal Public Health Service regulations 42 CFR part 50, subpart F, and 45 CFR part 94. Potential conflicts of interest arise when a Gillette researcher participates in research, teaching, outreach, or public service activities, and the Gillette researcher, an immediate family member, or an associated entity have any reportable financial or business interest in the technology, process, product or other subject matter of the activity, or in any business supporting the activity. In general, a potential conflict exists if the Gillette researcher, immediate family member, or associated entity has a business or financial interest that could be enhanced based on the outcome of the activity. Some activities that raise potential conflicts of interest are ordinarily allowable following reporting and, where necessary, the implementation of a management plan. Other activities and external relationships require case-by-case review and only some of the specific relationships may be approved. In such cases, management plans are likely to be required.

Procedure:***Training/Reporting***

Investigators must complete Gillette's conflict of interest training or an accepted conflict of interest training from the investigator's primary affiliation and disclose significant financial or business interests via a disclosure survey annually, regardless of the researcher's date of hire. A renewal notice will be sent to each investigator. New investigators will need to self-register for conflict-of-interest training by sending an email to Research@gillettechildrens.com and requesting the necessary information. An investigator must complete the training and submit a disclosure survey before undertaking any research, prior to Institutional Review Board (IRB) approval. If training and disclosure are not completed, investigators will not obtain IRB approval nor be allowed to submit a project for funding. If conflicts are disclosed, a management plan may be required.

Significant financial or business interests that require reporting include the following:

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1. Gillette researcher, an immediate family member or associated entity have, as of the reporting date, an equity interest in a business that is privately held or an aggregated equity interest in a publicly held company representing ownership of 5 percent or more, or a value of \$5,000 or more, as determined through reference to public prices or other reasonable measures of fair market value.
2. Gillette researcher, an immediate family member or associated entity have received an aggregated annual income of all types from a business over the last 12 months equal to or exceeding \$5,000.
3. Gillette researcher, an immediate family member or associated entity have received intellectual property income (e.g., royalties or licensing fees from patents or copyrights) over the last 12 months from a business that is equal to or exceeds \$5,000.
4. Gillette researcher or an immediate family member has a business interest.
5. Gillette researcher had an occurrence of travel paid for or reimbursed by a business entity, unless the trip was paid for or reimbursed by a governmental agency, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Note that the initial online disclosure survey does not require specific monetary amounts to be added to the various categories of potential conflict. However, if involved in a project at Gillette that has PHS funding **or** if it is determined that your circumstance may constitute a potential conflict of interest, then actual monetary amounts may need to be reported at a later point in time. This information will help determine whether a true financial conflict of interest exists and formulate a suitable management plan if needed.

Investigators are not required to disclose the following: (1) salary, royalties, or other compensation from Gillette, (2) income from seminars, lectures, or teaching sponsored by public or nonprofit entities, (3) income from participation on advisory committees, review panels, or at formal hearings for public or nonprofit entities, and (4) income from mutual funds and retirement accounts as long as the investigator does not directly control the investment decisions. Investigators should consult with the Research Department and/or the Legal Affairs Department if there is a question as to what needs to be disclosed. Investigators should always err on the side of complete transparency.

Whenever substantial changes occur that may alter the financial or business interests previously reported, an updated disclosure must be submitted within 30 days from the occurrence or circumstances creating a potential conflict.

All reports must be made promptly and forthrightly, must identify the potential conflict(s) of interest, and must provide sufficient and relevant detail for an adequate review of the circumstances or issue. Funding for a project will not be accessible to the researcher until a disclosure is reviewed and approval is given.

In addition to the reporting requirements set forth in this policy, various government agencies and sponsors may have additional reporting requirements. All Gillette researchers must comply with such additional requirements. For example, the NIH and other PHS entities require reporting the name of the entity of financial interest, the nature of the conflict and approximate monetary value, a description of how the financial interest is related to the research, why it is believed to constitute

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a financial conflict of interest, and the key elements of the plan to manage the conflict. Disclosures by investigators applying for or receiving funding from any of the PHS agencies will be evaluated by PHS rules regarding significant financial interests in non-Gillette entities. When submitting a paper for publication or an abstract for a conference presentation, investigators must disclose to the editor any financial or business interest that may be related to the publication. This provision also applies to release of information to news media.

Disclosure of relevant financial or business interests must also be made by any Gillette researcher who makes an appearance, either in person, or by way of a written communication, before any public body, commission, group or individual, to present facts or to give an opinion regarding any issues or matters up for consideration, discussion, or action.

When Gillette researchers participate in sponsored research involving sub-grantees, contractors, or collaborators outside of Gillette, Gillette, to the extent required by the sponsor, will take reasonable steps to ensure that investigators working for these outside entities comply with appropriate conflict of interest reporting and review requirements. These steps may include requiring the investigators to comply with Gillette's policy or obtaining written assurances from the outside entity that its COI policy complies with applicable federal regulations or sponsor policies on conflict of interest.

Review and Management of Potential Conflicts of Interest

Subsequent to reporting, and depending on the nature of the matter, members of the Research Conflict of Interest group (made up of the Sponsored Projects Administrator, Director of Research, Associate Medical Director of Research, and Compliance and Privacy Counsel that report to Research Governance) will review the submitted disclosure information and will arrive at a determination regarding whether a potential conflict exists. Where subject matter expertise is necessary, the Committee may seek the assistance of ad hoc members.

If it is determined that a significant conflict of interest exists, an appropriate management plan will be designed in consultation with the Gillette researcher with measures to manage, reduce, or eliminate any such conflict. These management plans will be shared with the investigator and submitted with the IRB application and stored with the staff member's Research Essential Documents for future reference. Management plans are intended to maintain transparency and decrease perceptions of influence, and may include, but are not limited to:

- Appropriate public disclosure of significant financial interests to appropriate audiences;
- Adoption of specially created review procedures to ensure that conflicting interests do not compromise the integrity of the design, conduct or reporting of the funded research;
- Monitoring of the research by independent internal or external reviewers;
- Modification of the research plan;
- Withdrawal from all or a part of a funded research project;
- Divestiture or modification of the relationship with a business or industry, if necessary; and
- Severance of relationships that create actual or potential conflicts.

Disclosure of the management plan may be made to appropriate audiences or committees, which may include patients, students, a department, IRB, or other audiences as necessary. Monitoring and oversight of conflicts of interest and management plans will be conducted by the Research Conflict of Interest group with Research Governance oversight.

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Common sense must prevail in the interpretation of the provisions in this policy. That is, if a reasonable person would question a business or financial relationship, it should be disclosed and approval sought for the proposed arrangement. If the investigator already has a management plan from another institution, the Committee will consider adopting this plan. They will obtain and review a copy of the management plan and determine whether it is appropriate for Gillette standards.

Enforcement/Sanctions

Gillette will not submit a proposal to a funding agency, execute a research agreement on behalf of an investigator, or provide ancillary compliance review approval on an IRB application for an investigator who has not completed the above requirements. Breaches of this policy include, but are not limited to, failure to disclose significant financial interests in a timely manner, intentionally filing an incomplete, erroneous or misleading disclosure, failure to complete the required training, or refusal to cooperate in the management, reduction, or elimination of conflicts of interest. These breaches will be grounds for disciplinary action consistent with hospital policies.

In any case in which the U.S. Department of Health and Human Services determines that a PHS-funded project whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by a Gillette researcher with a financial conflict of interest that was not managed or reported by Gillette as required by federal regulations, Gillette must require the researcher involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

If a Gillette researcher who is involved with research fails to comply with this policy, then a member of the Research Conflict of Interest Committee must promptly inform the sponsoring agency of the violation and of any corrective action taken or to be taken.

Reporting to Federal Agencies

Gillette will comply with any reporting obligations imposed by federal agencies.

Record Retention

Records of training of financial disclosures and actions taken to resolve conflicts will be kept for at least three years after the termination or completion of the study to which they relate, or after the final expenditure report of an award, or after the resolution of any civil, government or Gillette actions involving the records. All records will be maintained in a secure manner to protect confidentiality but will be accessible to sponsoring agencies as required by federal regulations or sponsor policies.

Related Documents: None

References:

- http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf - contains 42 CFR, Part 50, Subpart F and 45 CFR, Part 94 - Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought and Responsible Prospective Contractors
- 21 CFR 54 Financial Disclosure by Clinical Investigators



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THIS POLICY SUPERSEDES ANY PREVIOUS GILLETTE POLICIES OR PRACTICES.