Status **Active** PolicyStat ID **15745272**

Origination	01/2022	Owner	Trudy Wittenberg: 4388 Institutional Review Board Administrator
Last Approved	02/2025		
Effective	02/2025	Department	HRPP/Research
Next Review	02/2027		

Research: Conflict of Interest- AD.0157

PURPOSE

The purpose of this policy is to provide guidance on disclosing conflicts of interest as they pertain to research studies. It is intended that this conflict of interest policy be consistent with Food and Drug Administration (**FDA**) federal regulations, the Revised Common Rule, HIPAA, and good clinical practice. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

APPLICABILITY

This policy applies to Lakeland Regional Health's **Workforce** and personnel engaged in research.

POLICY

I. Conflicts of Interest

In its review, the **IRB** considers the disclosure of conflicts of interest that may affect the human subjects enrolled in the research, the integrity of the research, or the integrity of the **HRPP**. For the HRPP and the IRB, the disclosure of conflicts goes beyond investigator financial conflicts and includes institutional conflicts of interest, real or apparent, that could affect the research, the rights or safety of the research subjects, or the integrity of the HRPP. The HRPP standards regarding conflicts of interest apply equally to all research whether the study is sponsored (i.e., funded by an external organization) or non-sponsored.

II. Research Personnel Conflict of Interest

A. LRH recognizes that collaboration of principal investigators (PIs), sub-investigators, and other Research Personnel with drug, medical device, and biologic manufacturers is essential to the production of effective and efficient research and the development of improvements in patient care. However, such collaboration may give rise to actual, potential, and perceived conflicts of

interest for clinical researchers. Conflicts of interest in the research setting may create professional bias, potentially impacting the selection of research subjects; the collection, analysis, and interpretation of research data; reporting of adverse events; and publication of research results.

B. LRH seeks to ensure that all investigators and other personnel involved in conducting research within LRH are able to carry out their responsibilities and obligations to protect the rights and welfare of human subjects.

C. Conflict of Interest (COI): A conflict of interest exists when an investigator or other Research Personnel's financial, personal, or professional interests would potentially or actually compromise their professional judgment in conducting or reporting research, OR may be perceived as compromising the investigator or other Research Personnel's professional judgment in conducting or reporting research. Financial, personal, or professional interests include not only the Research Personnel's own interests, but also those of his or her immediate family. (See the definition of "immediate family member" below.) The examples below provide a non-exclusive list of circumstances that constitute a conflict of interest:

    1. The study involves a drug or device invented by the investigator, other Research Personnel, or a member of their immediate family.
    2. The study is sponsored by an entity with whom the investigator, other Research Personnel, or a member their immediate family have a paid consulting or advising relationship.
    3. The investigator, other Research Personnel, or a member of their immediate family will receive special compensation or increased compensation for a favorable study outcome.
    4. The investigator, other Research Personnel, or a member of their immediate family holds licensing or intellectual property rights in the drug or device to be studied.
    5. The investigator, other Research Personnel, or a member of their immediate family holds any ownership interests including stocks, bonds, or stock options in the sponsoring organization.
    6. The investigator, other Research Personnel, or a member of their immediate family has or will receive salaries, royalties and other payments for services (e.g., consulting fees, honoraria, study design, management position, independent contractor, service on advisory or review committees, board membership, seminars, lectures, or taching engagements) from the study sponsor for any studies and, in particular, the study under review.
    7. The investigator, other Research Personnel, or a member of their immediate family holds a management or fiduciary position (such as serving as an officer or director) with the research protocol's sponsor.
    8. The investigator, other Research Personnel, or a member of their immediate family will receive payments (e.g., gifts, cash, loans) in exchange for referring or enrolling human subjects in a research study.

D. Financial Conflict of Interest (FCOI): Financial Conflict of Interest (FCOI) means a Significant Financial Interest (SFI) that is reasonably related to the research or the investigator's LRH responsibilities and might compromise or be perceived to affect the design, conduct or

reporting of the research, including the protection of the human research subjects.

E. Institutional Conflict of Interest: The possibility that financial interests of LRH or a LRH official acting within his or her authority on behalf of the institution might affect or reasonably appear to affect institutional processes for the design, conduct, reporting, review, or oversight of human subjects research.

F. Investigator: Means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include, for example, collaborators, or consultants.

G. Immediate Family: For the purposes of consistency with LRH policy, Employee Ethics/Conflict of Interest- AD.0103, the IRB's definition of immediate family includes the following individuals:

1. A spouse or domestic partner;
2. Child or step-child;
3. Parent or step-parent;
4. Sibling or step-sibling; or
5. Grandparents and grandchildren.

- The individual responsible for completing the IRB protocol process must have knowledge of any potential conflicts of interest for all persons named on the protocol as well as members of their immediate families.

H. Remuneration: Includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships).

I. Significant Financial Interest (SFI) (42 CFR 50.603): Identified when any of the following is true:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration 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 Five Thousand Dollars ($5,000.00). For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds Five Thousand Dollars ($5,000.00) 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); or
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
4. Investigators also must disclose 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), related to

their institutional responsibilities 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 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. If applicable, the investigator must disclose the following:

a. The purpose of the trip;

b. The identity of the sponsor/organizer; and

c. The destination and the duration of the trip.

5. In addition to the above, LRH requires disclosure by the Investigator if Investigator holds a position as a director, officer, partner, trustee, or employee or any other position held within the sponsor.

J. Exclusions:

1. Salary, royalties, or other remuneration paid by LRH to the Investigator if the Investigator is currently employed or otherwise appointed by LRH.
2. Intellectual property rights assigned to LRH and agreements to share in royalties related to such rights.
3. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
4. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined in 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.
5. Income from service on advisory committees or review panels for a federal, state, or local government agency, or 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.

PROCEDURE

I. Disclosure of Conflicts of Interest

A. All Research Personnel must disclose any actual, potential, or perceived conflicts of interest and Significant Financial Interests (SFIs).

1. All Research Personnel must provide the Conflict of Interest & Compliance Statement for Research Personnel form.
2. The disclosure must be updated if, after the initial submission of the protocol, study personnel become aware of a change in their actual, potential, or perceived conflicts of interest.
3. Changes that create a new Significant Financial Interest or raise the level of an existing Significant Financial Interest must be reported to the IRB within ten (10)

working days of the change.

4. Must submit annually, per each study.

B. Research Consent Form

The investigator must submit a copy of the consent form with the identified conflict(s) of interest for approval by the IRB. The IRB will make a determination regarding the level of disclosure required in the consent process.

II. Evaluation of Conflicts of Interest

A. Administrative Evaluation

1. Upon receipt of a Conflict of Interest & Compliance Statement for Research Personnel form, the IRB Administrator or designee will review the form to ensure that it has been completed properly and will determine if any Research Personnel have disclosed a Significant Financial Interest.
2. If the investigator does not disclose a Significant Financial Interest, the submission will be included with the IRB protocol for review.
3. If the investigator discloses a Significant Financial Interest, the IRB Administrator or designee will determine whether a COI management plan has already been approved for the researcher.
4. If an approved COI management plan exists for the investigator, the review of the IRB submission will proceed. The reviewing IRB will be apprised of the COI management plan, which the IRB may amend as necessary. The IRB-approved plan will be implemented for the research protocol.
5. If an approved COI management does not exist for the investigator, the IRB Administrator will notify the IRB Chair who will evaluate the COI and recommend a management plan.

B. Evaluation of Significant Financial Interests

1. The IRB Chair will assess the information provided to determine whether the disclosure for any Research Personnel or immediate family members meets the definition of a Significant Financial Interest.
2. In order to make a determination as to whether a Significant Financial Interest constitutes a conflict of interest, the IRB Chair may request additional information, as needed. Requests for further information will be made in writing, and investigators will be granted thirty (30) days to respond to the request. In the event Research Personnel fail to respond to the request, the Chair may take appropriate action, including extending the deadline for submission or declining approval of the research protocol.
3. It is the responsibility of the PI to carry out the conflict management plan for all Research Personnel according to an agreed-upon time line specified in the conflict management plan.

C. IRB Evaluation

1. Financial Conflicts of Interest
    a. The IRB may accept or decline the determinations of the Chair. The IRB is ultimately responsible for the rights and welfare of human subjects, and if it is not satisfied that the conflict management plan will protect the rights and welfare of human subjects, the IRB shall independently review the Significant Financial Interests and either refuse to approve the study or recommend additional or different requirements to manage, reduce, or eliminate the conflict of interest.
    b. If the IRB determines additional disclosure or measures to protect subjects are necessary, the IRB will notify the investigator of the requested revisions to the research protocol, and/or consent document/process as part of the review.
    c. The final conflict management plan will be documented.

D. Other Conflicts of Interest
    1. As part of its normal review process, the IRB will review all other conflict of interest disclosures that do not meet the definition of a Significant Financial Interest. When evaluating a conflict of interest disclosure, the IRB will determine if the investigator or any Research Personnel have personal, professional or financial interests that constitute a conflict of interest. Specifically, the IRB will look at whether:
        a. The study involves a drug or device invented by the investigator, other Research Personnel, or a member of their immediate family.
        b. The study is sponsored by an entity with whom the investigator, other Research Personnell, or a member of their immediate family have a paid consulting or advising relationship.
        c. The investigator, other Research Personnel, or a member of their immediate family will receive special compensation or increased compensation for a favorable study outcome.
        d. The investigator, other Research Personnel, or a member of their immediate family holds licensing or intellectual property rights in the drug or device to be studied.
        e. The investigator, other Research Personnel, or a member of their immediate family holds any ownership interests including stocks, bonds, or stock options in the sponsoring organization.
        f. The investigator, other Research Personnel, or a member of their immediate family has or will receive salaries, royalties and other payments for services (e.g., consulting fees, honoraria, study design, management position, independent contractor, service on advisory or review committees, board membership, seminars, lectures, or teaching engagements) from the study sponsor for any studies and, in particular, the study under review.
        g. The investigator, other Research Personnel, or a member of their immediate family holds a management or fiduciary position (such as serving as an officer or director) with the research protocol's sponsor.

h. The investigator, other Research Personnel, or a member of their immediate family will receive payments (e.g., gifts, cash, loans) in exchange for referring or enrolling human subjects in a research study.

2. In order to make a determination as to whether any Research Personnel's interest(s) constitutes a conflict of interest, the IRB may request additional information, as needed. Requests for further information will be made in writing with thirty (30) days to respond to the request. In the event there is no response to the request, the IRB may take appropriate action, including extending the deadline for submission or declining approval of the research protocol.
3. If the IRB determines the existence of a conflict of interest, it will determine whether or not the conflict can be eliminated, reduced, or managed.
4. All determinations by the IRB will be communicated to the PI in writing.

III. Managing Conflicts of Interest

A. LRH recognizes that many conflicts of interest may be managed effectively either through the elimination of the conflict or through the management of the risks associated with the conflict for the purpose of protecting human subjects.

B. Following an evaluation of the conflict of interest disclosure, the Chair or IRB may impose one or more conflict management strategies in order to reduce or eliminate the likelihood that a researcher's personal, professional, or financial interests would interfere with his or her ability to conduct research at LRH objectively.

C. Conflict management strategies may include, but are not limited to the following:

1. Disclosure of personal, professional, or financial interests to all potential research study participants, including disclosure on the research consent form.
2. Public disclosure of personal, professional, or financial interests in all publications pertaining to the research, including publication of study data.
3. Requesting that Research Personnel and/or immediate family members place any equity interests in escrow until a date specified by the IRB, requiring the investigator or Research Personnel to divest such interests.
4. Requesting that Research Personnel and/or immediate family members resign from any positions that may give rise to potential conflicts, including consulting and fiduciary positions.
5. Limiting the role of the Research Personnel in conducting all aspects of the study including recruitment; enrollment; clinical services; or collecting, entering, analyzing, or publishing study data.
6. Requiring the PI to appoint an impartial individual or group with no interest in the outcome of the study to oversee the research activities.

D. If the IRB imposes one or more conflict management strategies, the IRB must provide the investigator with a Conflict Management Plan, specifying the management strategies required of all personnel on the study. The investigator and other Research Personnel with a conflict must affirm that they agree to abide by the terms of the Conflict Management Plan. The IRB Office must receive this affirmation of the Conflict Management Plan before final study

approval will be granted.

E. If a conflict of interest cannot be managed, the IRB may decline the research protocol.

IV. Sanctions

A. Sanctions may be imposed on Research Personnel who fail to abide by the guidelines and procedures set forth in this policy. Sanctions may be imposed if Research Personnel:

1. Fail to submit necessary disclosures.
2. Intentionally submit erroneous or inaccurate information.
3. Fail to abide by any conflict management strategies imposed by the IRB and agreed to by the PI.

B. Sanctions may include, but are not limited to the following:

1. A letter of reprimand.
2. Imposition of additional conflict management strategies.
3. Withdrawal of IRB approval of the study.
4. Notification of all regulatory agencies and the study sponsor.
5. Suspension of enrollment of human subjects in the research study.

V. Incentive Payments

A. It is LRH's policy not to accept or permit incentive bonus payments directly to investigators, study coordinators, research administrators, or other Research Personnel. In addition, health care professionals shall not offer or accept "finder's fees". These types of payments generally are made directly to physicians and are not referenced in any clinical study agreement. Personal monetary payments, made directly to investigator or support staff, are not permissible.

B. The following are common types of incentives offered by clinical study sponsors to researchers (or used in clinical trial agreements) that are prohibited by this policy:

1. Finder's Fees: Payment to physicians or health care professionals for referring subjects to investigators.
2. Bonus Payments: Payments to the investigator for enhanced enrollment at any time during the course of the study.
3. Bonus Payments to Study Coordinators/Enrollers: Payments made to study coordinators for enhanced enrollment. Sometimes payments are made directly from the company and are not associated with contract costs.

C. It is permissible to accept additional per-subject payment for actual costs associated with additional procedures required due to changes to the original protocol. Studies sometimes demand more effort than originally anticipated, so additional payments can be made to offset these costs. These costs may include additional personnel time required to actively enroll subjects, to evaluate eligibility of support, and to conduct follow-up visits. Payment for these costs must be reflected in the study agreement.

DEFINITIONS

FDA: Food and Drug Administration

HRPP: Human Research Protections Program

IRB: Institutional Review Board

Research Personnel: Refers to all individuals designing research, directing research, serving as a PI or sub-investigator, enrolling research subjects (including obtaining subjects' informed consent or screening potential subjects), or making decisions related to eligibility to participate in research, analyzing or reporting research data, analyzing or reporting adverse events, or submitting manuscripts concerning the research publication

Workforce: All LRH employees, volunteers, trainees/students, contractors, and medical staff.

REFERENCES

U.S. Food and Drug Administration. Code of Federal Regulations Title 21.

Approval Signatures

Step Description	Approver	Date
	Danielle Drummond: 0001 President & Chief Executive Officer - LRHS	02/2025
	Jonn Hoppe: 1011 Executive VP, Chief Legal Officer-General Cou	02/2025
	Timothy Regan: 0009 President - LRMC/Chief Medical Officer	02/2025
	Renee Reed: 4064 Senior Attorney	02/2025
	Michael Spake: 0057 SVP - External Affairs/Chief Compliance	01/2025
	Deana Nelson: 4080 SVP - Administration and Corporate Initiative	01/2025

Andrew Bugajski: 4387 AVP - Research and Sponsored Studies	01/2025
Georgia Ann Keriazes: 0729 QI/ Due Pharmacist	01/2025
Trudy Wittenberg: 4388 Institutional Review Board Administrator	01/2025