DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Conflict of Interest for Clinical Investigators	Policy #: CRP-1009
DEPARTMENT: DHR Health Institute for Research & Development	PAGE: 1 OF: 11
	EFFECTIVE: 02/19
APPROVED BY: Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS)	REVIEWED/REVISED: 02/19, 02/20, 11/20, 01/21, 04/21, 05/21, 03/22

Purpose:
DHR Health Institute for Research & Development strives to follow industry standards for managing and minimizing potential conflicts of interest. Investigators may have other reporting obligations under the below-referenced regulations, local law, and/or other governing bodies such as Institutional Review Boards (IRBs).

DHR Health Institute for Research & Development expects investigators to disclose potential conflicts of interest involving research staff or immediate family members (including spouses and dependent children) regardless of funding source. The financial and non-financial interests of investigators, staff and immediate family members must be reported to DHR Health Institute for Research & Development IRB Development committee and the IRB of record for each study.

APPLIES TO
This policy applies to the following potential research investigator; Physician staff employed by RMF and its affiliates; staff employed by DHR Health and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; staff and physicians of non-academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; Physicians with privileges to practice medicine in DHR Health, Physicians and staff employed by Starr County Memorial Hospital and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; staff and physicians of non-academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; Physicians with privileges to practice medicine in Starr County Memorial Hospital and its affiliates.

Definition:

Policy:
It is the investigator's responsibility to ensure compliance with all applicable reporting requirements with respect to conflicts of interest. It is the responsibility of the staff of the DHR Health Institute for Research & Development to ensure minimal or no conflict of interest is present before approval of the project/study. Similarly, any conflicts of interest in any capacity (i.e. Financial, etc) should be reported according to regulations and guidelines. DHR will make this policy available via a publicly accessible website.

When research is funded by the Public Health Service of the U.S. Department of Health and Human Services (and any components of PHS, such as the National Institutes of Health) (PHS) regulations at 42 CFR 50, Subpart F for Financial Conflicts of Interest and 45 CFR 94.5 – Management and reporting of financial conflicts of interest will apply and take priority in place of this policy.

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Procedure:

A. Financial Disclosure for Sponsors and Investigators

DHR will inform and provide a copy of this policy to each Investigator.

Below is a list of conflicts that must be reported to DHR Health Institute for Research & Development IRB of record no later than the time of application for all funded research.

1. Financial arrangement based on outcome of the study: Any financial arrangement with the sponsor of the study, whereby the value of the compensation for conducting the study could be influenced by the outcome of the study.
2. Significant Payment (exclusive of the costs of conducting research): Any significant payment of more than $25,000 made on or after February 2, 1999 from the sponsor to the investigator such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, honoraria, or paid authorship.
3. Financial Conflict of interest: a significant financial interest that could directly and significantly affect the design, conduct, or reporting of all funded research.
4. Financial Interest: anything of monetary value, whether or not the value is readily ascertainable. Intellectual property rights or proprietary interests: Any proprietary interest (including patents and copyrights) in the product tested for a project upon receipt of income related to such interest.
5. Any significant financial interest in the sponsor of the study: “Significant financial interest” is defined as follows:
   a. For non-publicly traded corporations and other entities: the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, 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).
   b. For any publicly traded entity: the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. 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; ***The following does not need to be disclosed: any ownership or other interest, which is a sub-set of a mutual fund or other investment vehicle, for example a 401K or other non-actively managed retirement fund that the individual has no control over and does not direct.***
6. Employment or executive relationship: Any employment or executive relationship with the sponsor of the study. Please note that any payment amount over $10,000 in the past 12 months must be disclosed

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7. Enrollment or recruitment bonuses or finder's fees: Any enrollment bonuses, finder's fees, and/or gift of equipment to the site or individual from the sponsor.
   - Enrollment bonus payments do not include per-participant payments made by Sponsors to accelerate enrollment (e.g., for additional advertisements). Payments that reimburse an individual at fair market value for his/her efforts and costs associated with the research may be acceptable.
   - Finder's Fees policy: DHR defines a finder's fee as financial or non-financial incentives paid from a PI or a Sponsor to a person who is not a member of the study staff, nor otherwise affiliated with the study who refers a potential participant. DHR deems acceptable the provision of finder's fees to individuals who do not have a fiduciary relationship with the potential participant and who are not likely to create inequitable selection of research participants. An individual with such a relationship toward a potential participant would be in a position of trust or authority, such as a physician or parent. However, a finder's fee is not acceptable if it is found to interfere with providing prospective participants with sufficient opportunity to consider whether to participate or otherwise increase the possibility of coercion or undue influence on investigators or participants.
8. Other financial or non-financial relationship: Any other financial or non-financial relationship with the sponsor of the study that may create an actual or apparent conflict of interest.
9. Sponsored Travel: any reimbursed or sponsored travel (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 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. Any travel disclosure shall include:
   a. Purpose of the trip;
   b. Identity of the sponsor/organizer;
   c. Destination;
   d. Duration; and
   e. Monetary value

Investigators must complete ***DHR Health Institute for Research & Development Disclosure of Financial Interests and Conflict of Interest Statement Form*** for every research project. The form must be reviewed and approved by the DHR Health Institute for Research & Development prior to the conduct of a research project. This form must be completed annually, and if necessary updated accordingly, by each Investigator participating in funded research.

Financial Interests listed in 42 CFR 50.603(3) are not considered significant financial interests and need not be disclosed.

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If any of the above-described conflicts of interest exist, the Institution must develop a ***Management Plan***. Examples of the conditions and restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing research);
- For research projects involving human subjects, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the financial 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 financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

DHR will require disclosure of reported conflicts of interest in the applicable consent form(s) provided to patients and/or human subjects.

An Investigator participating in funded research must submit an updated disclosure of significant financial interests within thirty (30) days of discovering or acquiring (e.g. through marriage, purchase or inheritance) a new significant financial interest.

If in the course of an ongoing funded research project, an Investigator (or new Investigator) discloses a significant financial interest, DHR Health Institute for Research & Development's designated official shall within sixty (60) days proceed with the following:

- Review the disclosure of the significant financial interest;
- Determine whether it is related to funded research;
- Determine whether a financial conflict of interest exists; and if so, implement on at least an interim basis, a management plan that shall specify the actions that have been taken, and will be, taken to manage such financial conflict of interest.

During the identification, resolution, and management of conflicts, DHR Health Institute for Research & Development will take reasonable steps to protect the specifics of any reported financial information

but cannot guarantee confidentiality. Such information might be disclosed to a governmental agency or other parties, such as the sponsor, CRO, IRB and/or the FDA, or in the case of PHS research may

have to be publicly disclosed in accordance with 42 CFR 50.606(c) and 45 CFR 94.5. Please note that failure to disclose possible conflicts of interest is a serious offense and could lead to suspension or termination of project approval.

DHR Health Institute for Research & Development shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the research.

B. Failure to Disclose or Identify Conflicts of Interest

Whenever DHR Health Institute for Research & Development identifies a significant financial interest that was not disclosed timely by an Investigator, or for whatever reason, was not previously reviewed by DHR Health Institute for Research & Development during an ongoing research project (e.g., was not timely reviewed or reported by a sub recipient), DHR's designated official(s) shall within sixty (60) days:

- Review the significant financial interest
- Determine whether it is related to research; and
- Determine whether a financial conflict of interest exists and, if so:
    - Implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward; and
    - Within one hundred and twenty (120) days of DHR Health Institute for Research & Development determination of non- compliance, complete a retrospective review of the Investigator's activities and the research project to determine whether any or a portion of research, conducted during the time period of noncompliance, was biased in design, conduct, or reporting of such research.

C. Retrospective Reviews

DHR will document the retrospective review which shall include, but not necessarily limited to, all of the following key elements:

- Project number
- Project Title
- Project Director/Principal Investigator (PD/PI) or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)

- Findings of the review; and
- Conclusions of the review.

Based on the results of the review, if appropriate DHR will update the previously submitted FCOI report, specifying the actions that will be taken to manage the conflict going forward. If bias is found, and research is funding by PHS, DHR Health Institute for Research & Development will notify the PHS Awarding Component[1] promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must comply with 45 CFR 94.5(a)(3)(iii) and 42 CFR 50 Subpart F. Thereafter DHR Health Institute for Research & Development will submit FCOI reports annually.

Whenever a management plan is implemented, DHR Health Institute for Research & Development shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the research project.

D. Website Accessibility for PHS-funded research

Before DHR Health Institute for Research & Development expends any funds under a PHS-funded research project, DHR Health Institute for Research & Development will upload, via a publicly accessible web site or written response to any requestor within five (5) business days of a request, of information concerning any significant financial interest disclosed to DHR Health Institute for Research & Development that meets the following:

- The financial interest was disclosed and is still held by key personnel.
- DHR Health Institute for Research & Development determines that the financial interest is related to PHS-funded research.
- DHR Health Institute for Research & Development determines that the financial interest is a financial conflict of interest.
- The information to be made available will comply with **45 CFR 94.5(5).**
- DHR Health Institute for Research & Development will update such information at annually.
- DHR Health Institute for Research & Development will update the website within sixty (60) days upon receipt of a new or additional significant financial interest of senior/key personnel for PHS-funded research not previously disclosed. The website will contain the following statement:

  "The information provided is current as of [insert date] and is subject to updates, on at least an annual basis and within sixty (60) days of DHR Health Institute for Research & Development's identification of a new financial conflict of interest."

[1] The organizational unit of the PHS that funds the research that is subject to this subpart.

This statement shall also be provided in written responses to requests for information.

DHR Health Institute for Research & Development will keep such information available for written responses or for posting on the website for at least three (3) years from the date the information was most recently updated.

E. Reporting Financial Conflicts of Interest for PHS-funded research

Before DHR Health Institute for Research & Development expends any funds for a PHS-funded research project, DHR Health Institute for Research & Development shall provide to the PHS Awarding Component a Financial Conflict of Interest (FCOI) report regarding any Investigator's significant financial interest found by DHR Health Institute for Research & Development to be conflicting and ensure that DHR Health Institute for Research & Development has instituted a management plan in accordance with 45 CFR 94.5. If DHR Health Institute for Research & Development eliminates a financial conflict of interest before spending any PHS-awarded funds, DHR Health Institute for Research & Development shall not submit a report to the PHS Awarding Component.

If a conflict is identified after the report is submitted, DHR Health Institute for Research & Development shall provide to the PHS Awarding Component, within sixty (60) days a report with the conflict and ensure that DHR Health Institute for Research & Development has a management plan in accordance with 45 CFR 94.5 and 42 CFR 50 Subpart F

Any FCOI report or mitigation report required to be given once a new conflict is identified will contain enough information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of DHR Health Institute for Research & Development's plan. The report will contain the information listed in 45 CFR 94.5 (b)(3).

For all previously reported conflicts for ongoing PHS-funded research projects, DHR Health Institute for Research & Development will provide to the PHS Awarding Component an annual FCOI report that addresses the conflict status and any management plan changes for the duration of the PHS-funded research project. It will specify whether the financial conflict is still being managed or explain why it no longer exists. DHR Health Institute for Research & Development will provide annual reports for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

F. <u>Conflict of Interest Training</u>

Each investigator must undergo training on this policy before engaging in any funded research and at least every two (2) years. Training shall also be required when the following occur:

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- DHR Health Institute for Research & Development revises its financial conflict of interest policy or procedures in any manner that affects Investigator requirements.
- An investigator is new to DHR Health Institute for Research & Development; or
- DHR Health Institute for Research & Development determines that an investigator is not in compliance with this policy or a management plan.

G. Sub recipients

DHR Health Institute for Research & Development shall ensure that if it carries out any PHS-funded research through a sub recipient, that any sub recipient Investigator complies with 42 CFR 50.604(c).

H. Designated Official

DHR Health Institute for Research & Development shall designate an official to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, PHS-funded research.

DHR Health Institute for Research & Development shall provide such official with appropriate guidelines to determine if an Investigator's financial interest is related to PHS-funded research and if related, whether a financial conflict of interest exists.

A relation exists when the significant financial interest could be affected by the research.

A conflict of interest exists when DHR Health Institute for Research & Development (through the official) determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

I. Record Retention

DHR Health Institute for Research & Development will maintain all records relating to all Investigator disclosures of financial interests and DHR Health Institute for Research & Development's review of, and response to, such disclosures (whether DHR Health Institute for Research & Development determined a financial conflict of interest) and all actions under DHR Health Institute for Research & Development's policy or retrospective review, if applicable for at least three (3) years from the date the final expenditures report is submitted to PHS.

J. Remedies

If an Investigator fails to comply with this policy or a management plan implemented pursuant to this policy, or a conflict of interest and/or management plan appears to have biased the design, conduct, or reporting of the research, DHR Health Institute for Research & Development will notify the Awarding Component of the corrective action taken or to be taken. DHR Health Institute for Research & Development will cooperate with any recommendations or requirements by the Awarding Component to remedy the situation.

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DHR Health Institute for Research & Development shall cooperate with the Awarding Component and/or HHS on any inquiries related to financial conflicts of interest for funded research, specifically that which is listed in 45 CFR 50.606 (b).

Conflict of Interest (For IRB Members Only)

Disclosure

The IRB leadership, staff and affiliated IRB members are required to disclose significant financial interests (SFI) in accordance with DHR Health Institute for Research and Development Conflict of Interest policies.

IRB Members

IRB members who are considered unaffiliated with the institution will not be required to complete the standard conflict of interest disclosure form. These members will be required to sign a statement at the time of their orientation indicating that the conflict of interest policy has been provided to them.

To ensure understanding of Conflict of Interest (COI) issues, all members will be provided with the DHR Health Institute for Research and Development definitions of COI at the time of their orientation. In addition, the IRB COI Policy will be reviewed on an annual basis with all committee members to ensure they are aware of acceptable COI thresholds.

Potential conflicts of interest (COI) include but are not limited to:

- being a listed investigator (or having an immediate family member including the spouse, dependents, and all members of the employee's household including domestic partners listed as an investigator);
- having a significant financial interest (or having an immediate family member with such an interest) in the sponsor of the research or the technology being evaluated; or
- having any other conflict that might be perceived to inhibit a fair and unbiased review of the research.

Reviewer Assignment

The IRB Chair or Co-Chair will not review or approve an exempt/expedited research study in which s/he has a conflict of interest.

No IRB reviewer will be assigned to review a research study in which s/he has a conflict of interest.

Consultants

Consultants to the IRB will be asked, at the time they are contacted to review a research study, if they (or a member of their immediate family) have a conflict with the study on which they are being asked to

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consult. No consultants will be assigned to review a research study in which s/he has a conflict of interest.

Investigators

Research investigators are not permitted to participate in decisions relating to the selection of IRB members responsible for performing the review of their research studies.

Investigators must disclose if they have any of the significant financial interests listed in the COI section of the protocol application that are related to the research covered by the IRB protocol.

Investigators who have a financial conflict of interest (FCOI) with research covered under an IRB protocol must agree to a Conflict of Interest Management Plan (CMP) developed by the Office of Human Research Protection Program.

In the unlikely event that the IRB is not in agreement with the proposed COI management plan and an agreement cannot be reached following the above procedures, the decision to grant IRB approval of the protocol remains with the IRB. This includes an assessment (for the purpose of protecting the rights and welfare of the human subjects) of the COI provisions under which the research would be conducted.

Placement of Study on Agenda

No IRB reviewer or consultant will be assigned to review a research study in which s/he has a conflict of interest.

In the event that the IRB Chair is a listed investigator on the study submission, or holds a significant interest in the sponsor of the research being evaluated, the IRB Chair will be asked to step out of the room during the review, discussion and vote of the research submission. The Co-Chair will then act as the Chair for that portion of the meeting and will review and approve the minutes related to the study where the conflict exists.

Evaluations of Potential Conflicts at Meetings

IRB members and consultants are polled upon initiation of each IRB meeting to determine if they (or a member of their immediate family) are a listed investigator on any research study being reviewed at the meeting, or if they (or a member of their immediate family) hold a significant financial interest in the sponsor of any research study or any technology being evaluated in a research study being reviewed at the meeting or if any other potential conflicts exists.

Abstentions from Deliberations

IRB members and consultants will abstain from participation in any IRB deliberations or approval decisions relating to a research study in which they (or a member of their immediate family) have a potential financial

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conflict-of-interest.

IRB members and consultants will absent themselves from the IRB meeting room during IRB deliberations and decisions relating to a research study in which the individual (or a member of his/her immediate family) is listed as an investigator or has a potential non-financial conflict (e.g., consultant on the project). An exception is to provide information specifically requested by the committee.

Documentation in Minutes
The absence of members or consultants due to a conflict (i.e., a listed investigator, financial or other conflict) during the discussion of the research protocol and the vote will be documented in the minutes of the full board IRB meeting to include the reason for their absence.