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Area (Category)	Organization
Applicability	Hoag Memorial Hospital Presbyterian
Keywords	Clinical Research

Conflict of Interest in Research Conducted at Hoag

PURPOSE:

The purpose of this policy is to outline the federal requirements pertaining to "Objectivity in Research" and to establish the framework required to meet these requirements. The federal regulations are promulgated by the U.S. Public Health Service (PHS), which includes the National Institutes of Health (NIH), and which are published in 42 CFR Part 50 Subpart F and 45 CFR Part 94.

SCOPE:

This policy applies to any "Investigator" (see I under definitions) participating in clinical research in any Hoag owned or operated facility and is applicable to all sponsored clinical trials including any studies in which the Investigators receive finances outside of the Clinical Trial Agreement/budget. For a detailed definition of "clinical research", please see Policy labeled “Determination of IRB Review”.

AUTHORIZED PERSONNEL:

Clinical Research Office, Clinical Research Coordinators, Hoag Center for Research and Education, Principal and Sub-Investigators, Research Conflicts of Interest Oversight Committee.

1. DEFINITIONS - FOR PURPOSES OF THIS POLICY, THE FOLLOWING DEFINITIONS SHALL APPLY:

A. **Designated Official(s)** refers to the Director Clinical Research Finance & Regulatory and the

Director Clinical Research Operations who are jointly the designated officials responsible for obtaining and reviewing all disclosures of significant financial interests.

B. **Disclosure of Significant financial interests** means an Investigator's disclosure of significant financial interests to an Institution, which must be completed prior to engaging in research at Hoag

C. **Financial Conflict of Interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

D. **FCOI Report** means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

E. **Financial Declaration Form** shall refer to the form for reporting potential conflicts of interest that is required to be submitted at least annually by Investigators. The form may be either Hoag's or the Sponsor's, as long as it contains the required elements to determine if there is a Financial Conflict of Interest.

F. **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.

G. **HHS** means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

H. **Institutional responsibilities** means an Investigator's research responsibilities as defined by the Institution and this policy of financial conflicts of interest, which may include activities such as research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards. etc.

I. **Investigator** means the Project Director or Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, including research funded by the PHS, or proposed for such funding. This also includes sub-investigators, research nurses and clinical research associates. The amount the individual must disclose includes amounts owned by or paid to their spouse or dependent children.

J. **Immediate family** means a spouse, dependent child or domestic partner.

K. **Research Conflicts of Interest Oversight Committee (the "RCOI-OC")** is the committee responsible for the oversight, evaluation, and management of reported FCOI.

L. **Senior/Key Personnel** means the Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the institution in the grant application, progress report, or any other report submitted to the PHS by the institution under the regulation

M. **Significant Financial Interest** means:

    I. 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):

        a. 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 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure. 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;

b. 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 months preceding the disclosure, 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

c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

II. Investigators also must disclose the occurrence and value of any reimbursements for or sponsored travel expense including the purpose of the trip, sponsor/organizer, destination and duration)

III. The Significant Financial Interest term **does *not* include**:

I. Salary, royalties or other remuneration from Hoag

II. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities

III. Income from service on advisory committees or review panels for public or nonprofit entities;

a. An equity interest, for the purposes of this policy, is any investment or interest, such as stocks, stock options or other ownership interests, in the sponsor by the Investigator or his/her immediate family during the twelve month period.

2. POLICY:

A. Hoag allows and encourages outside relationships that serve to enhance Hoag's mission and scientific advancement and recognizes that inevitably such activities may lead to potential conflicts of interest as well as conflicts of commitment; as such, it is the responsibility of all individuals covered by this policy to disclose such activities, to act with integrity in conducting their research and to ensure such outside activities, whether through them directly, those of a family member, or any other personal associates, do not interfere with their obligations to their patients, or to Hoag.

B. All research conducted at Hoag Hospital and all of its related entities shall be compliant with applicable laws, regulations and these policies and related procedures.

C. All research Investigators shall disclose all financial conflicts of interest in accordance with this policy before research begins and immediately when a change in financial interest occurs. All investigators with conflicts will address those conflicts as determined by the Research Conflicts of Interest Oversight Committee (RCOI-OC) prior to beginning or resuming research activities.

D. Disclosures must include all Significant Financial Interests, including those of his/her immediate family (i) that would reasonably appear to affect or be affected by the research,

and (ii) in entities whose financial interests would reasonably appear to affect or be affected by the research.

E. All other potential or actual conflicts of interest or commitment must be disclosed as required under Hoag's general Conflicts of Interest and Disclosure of Certain Interests Policy, accessible via the WAVE or by contacting the Corporate Compliance office at corportatecompliance@hoag.org. or by calling (949)764-4427 (x44427).

3. FAILURE TO COMPLY:

A. Failure to comply with timely, accurate, and complete reporting or with appropriately addressing conflicts may result in immediate suspension of individuals and/or their participation in research projects and could result in canceling projects, terminating employees or removal of medical staff privileges. When an Investigator's failure to comply with this policy biases the design, conduct, or reporting of the research, the Director Clinical Research – Finance & Regulatory shall promptly report the corrective action taken to the appropriate funding agency, if required.

4. PROCEDURE

A. Clinical Research and Corporate Compliance Office Responsibilities

1. Policy Access. The Designated Officials and Principal Research Compliance and Conflicts of Interest will ensure this policy is made assessable both internally and externally.
    a. Internal Access: This policy will be assessable via PolicyStat available through Hoag's intranet (the WAVE).
    b. External (Public) Access: Hoag will maintain this Policy on Hoag's external website, as required under federal regulations.
2. Educate Investigators. The Designated Officials will ensure all investigators are Informed of this policy and their responsibilities related to it prior to the start of any Research, at least every 4 years thereafter, and any time there is an instance of non-compliance, or a material change to this Policy and Procedure.
3. Sub-Recipients. If subrecipients such as subcontractors or consortium members are involved, the Designated Officials will establish a written agreement including the requirement to comply with applicable regulations and this policy.
4. Disclosure. The Designated Official or his/her designee shall obtain a Financial Disclosure Form from each Investigator for each industry- sponsored and federally funded research study prior to study enrollment (required for study initiation in Policy labeled, Clinical Research New Study Approval Process) and annually thereafter.
5. Review/Management
    a. The Director Clinical Research – Finance & Regulatory, or his/her designee, shall conduct an initial review of all disclosures for completeness and the presence of any Significant Financial Interests.
    b. If a Significant Financial Interest exists the Director Clinical Research –

Finance & Regulatory, or his/her designee, will submit the disclosure(s) to the Corporate Compliance Office (CCO) and the RCOI-OC for further review and management.

c. The RCOI-OC will review all conflicts, whether, perceived, or actual and determine whether an Investigator's Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the research and if so shall make recommendations, as necessary, to manage, reduce or eliminate the FCOI.

d. Examples of conditions or restrictions that might be considered include, but are not limited to:

    i. Public disclosure of Significant Financial Interests;

    ii. Direct disclosure to research participants;

    iii. Monitoring of research by independent reviewers;

    iv. Modification of the research plan;

    v. Disqualification from participation in all or a portion of the research;

    vi. Divestiture of Significant Financial Interests;

    vii. Severance of relationships that create actual or potential conflicts; or,

    viii. Any other action deemed necessary by the RCOI-OC to manage, reduce, or eliminate the conflict of interest and potential bias.

e. The RCOI-OC shall complete its review and make its recommendations within thirty (30) days of disclosure.

f. If applicable, the Designated Officials will implement a written management plan and shall monitor compliance with the management plan throughout the duration of the research project.

g. As appropriate, the CCO will inform Legal.

6. Reporting. The Director of Clinical Research – Finance and Regulatory, or his/her designee will provide:

    a. To the RCOI-OC, initial and ongoing reports related to the management plan and monitoring activities.

    b. To the PHS agency, as required by federal regulations, prior to the expenditure of funds or in the case of subsequently identified FCOI within 60 days of identification. In addition, ongoing FCOI reports will be provided to the PHS Agency at least annually, for the duration of the study including retrospective reviews and mitigation reports, if applicable.

    c. To any requestor, within 5 business days of a request, as required under 42 CFR 50.605.

7. Record Retention. The Clinical Research Office (CRO) will maintain electronic records, on the Clinical Research share drive, of all financial disclosures covered by

this policy and of all actions taken to resolve FCOI for at least three years beyond the conclusion of the study or as otherwise provided under 45 CFR 74.53(b) exceptions, and shall make such information available, upon request, to HHS.

8. Enforcement. The RCOI-OC will address all breaches of this policy and make recommendations on appropriate action, within 60 days.
    a. Potential Non-Compliance Incudes, but is not limited to the following:
        i. Failure to comply with the disclosure requirement, whether by virtue of a refusal to unreasonably late responses or by his/her responding with incomplete or inaccurate information;
        ii. Failure to remedy conflicts; or
        iii. Failure to comply with conditions in a prescribed conflict management plan.
    b. Specific requirements for PHS-funded research
        i. Report to the PHS entity within 60 days,
        ii. Implement a management plan that specifies the actions that have and/or will be taken,
        iii. Complete a retrospective review of the Investigator's activities related to the research project, to determine if during the period of noncompliance there was evidence of a bias in the design, conduct, or reporting of the research.
            a. Document the retrospective review, as required under 42 CFR 50.605 and other applicable laws,
            b. If appropriate, update previously submitted FCOI report, and
            c. Submit a mitigation report to the PHS agency.
        iv. Potential conflicts that cannot be resolved may be elevated to the VP of Compliance for a decision or further action.

B. Investigator Responsibilities:
    1. Training
        a. Investigator will complete the required Conflicts of Interest Training prior to engaging in research and at least every 4 years thereafter, or as requested by Hoag, in accordance with 42 CFR 50.604 and any other applicable regulations.
        b. The required training is through the CITI on-line program accessed at www.citiprogram.org.
    2. Disclosures
        a. Initial Disclosure. Investigators are required to disclose to the CRO all Significant Financial Interests on the Disclosure Form provided to them by the Designated Officials.

i. In general, the disclosure must be submitted prior to the start of any research project approval.

ii. When federally funded disclosures must be submitted, at least, 7 business days prior to the date of Hoag's submission of the proposal for federally funded research.

b. Updates to Disclosure. The Financial Declaration Form must be updated immediately upon discovery or acquisition of a new significant financial interest, in no case later than 30 days, or annually, at a minimum, during the life of any research study.

i. Investigator's may access Hoag's Financial Declaration Form, available on Hoag's intranet (the WAVE), or by contacting either the CRO, or the Corporate Compliance department.

c. Travel Expenditures. Investigators must disclose the occurrence of any reimbursed travel or sponsored travel related to Institution responsibilities (including purpose of trip, sponsor/organizer, destination, and duration).

5. ADDITIONAL RESOURCES:

A. Resources on conflicts of interest (These are just a few of the many resources and guidance, regarding Conflicts of Interest, available on the internet).

I. Office of Research Integrity (ORI), Responsible Conduct of Research, Conflicts of Interest. https://ori.hhs.gov/education/products/columbia_wbt/rcr_conflicts/foundation/index.html

II. American Medical Association (AMA), Conflicts of Interest in Research. https://www.ama-assn.org/delivering-care/ethics/conflicts-interest-research

III. NIH GUIDE, Objectivity in Research, Volume 24, Number 25, July 14, 1995. Provides regulations establishing standards and procedures to be followed by institutions that apply for research to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research. https://grants.nih.gov/grants/guide/notice-files/not95-179.html

Reference: Applicable Regulatory Provisions and Agency Policies:

42 CFR 50 Subpart F Promoting Objectivity in Research (PHS)45 CFR Part 94 Responsible Prospective Contractors

National Science Foundation, NSF 22-1 Proposal and Award Policies and Procedure Guide, Effective October 4, 2021. https://www.nsf.gov/pubs/policydocs/pappg22_1/nsf22_1.pdf

Review and/or input for this procedure was given by the following:Clinical Research Office, Corporate Compliance Office, Hoag Legal Counsel.

Title and Version of IFU: n/a

All Revision Dates

3/22/2023, 2/14/2020

Attachments

Hoag_COI Clinical Research Financial Declaration Form 06APR11.doc

Approval Signatures

Step Description	Approver	Date
VP Approval	Marcy Brown: VP SR CHIEF OPERATIONS OFFICER	3/22/2023
Policy Management Approval	Carissa-Lyn Huang: POLICY MANAGEMENT SPECIALIST [KR]	3/22/2023
Owner Approval	Maggie Harris: PRINICPAL RESEARCH COMPLIANCE & CONFLICTS	3/22/2023