TITLE: Conflict of Interest In Research		POLICY/PROCEDURE NUMBER: IRB 2	
Author:	Jana L. Lacera, RN, MSA, CDM	Applicable To:	Key Personnel
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Page 1 of 8			

	CFNI		Community Hospital		St. Catherine Hospital		St. Mary Medical Center
X	Munster, Indiana	X	Munster, Indiana	X	East Chicago, Indiana	X	Hobart, Indiana

POLICY/PROCEDURE STATEMENT/PURPOSE:

The Community Healthcare System Central Institutional Review Board (CHS CIRB) is responsible for ensuring that its members that review research and the senior/key personnel that conduct research have no conflicting interest that might influence or make it difficult to exercise independent judgment in safeguarding the rights and welfare of human research subjects.

This policy reflects the significant changes to 42 CFR §50, Subpart F: Promoting Objectivity in Research. "This subpart promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest."

The Community Healthcare System and the CHS CIRB have chosen to apply the same standards of transparency to all research conducted within the system regardless of funding source.

This policy requires full reporting of a Key Personnel's significant financial interests that would reasonably appear to be affected by the individual's CHS CIRB membership or research activities. New reports or updated reporting of any relevant change in financial circumstances must occur prior to the CHS CIRB final approval of the research.

The CHS CIRB and the Community Healthcare System will protect the confidentiality of private investments and personal finances and will request information related only to financial relationships that might influence the objectivity of the Key Personnel.

Third parties may report alleged conflicts of interest to the Vice President of Corporate Compliance or the Value Line. Reports by a third party will be held in confidence by the Vice President of Corporate Compliance to the extent possible but must include appropriate and adequate information in order to be investigated. Reports made to the Value Line are reported to the Corporation anonymously.

The Policy will be made available to the public upon request by the CHS CIRB office within five (5) business days. The Policy and the Financial Conflict of Interest Disclosure Statement will be made available to the Key Personnel on the Intranet in the CHS CIRB Policy Folder and on the Intranet at the www.drcomhs.org website.

DEFINITIONS:

Conflict of Interest: Situations in which financial or other personal considerations, may compromise, or have the appearance of compromising, an Investigator's, Key Research Personnel's or a member of the CHS CIRB professional judgment in designing, conducting, interpreting, reporting or reviewing research

Conflict of Interest Disclosure Statement (Disclosure Statement): The document that is used by the CHS CIRB to elicit information regarding conflicts of interest, potential conflicts of interest, significant financial interests and potential significant financial interests of Key Personnel

Financial conflict of interest (FCOI): a significant financial conflict of interest that could directly and significantly affect the design, conduct, or reporting of research

Financial Interest: anything of monetary value, whether or not the value is readily ascertainable

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

Immediate Family: spouse, dependent children and a domestic or civil union partner.

Institution: any entity within the Community Healthcare System that is applying for or that receives research funding.

Institutional responsibilities: Key Personnel's professional responsibilities on behalf of the institution, and as defined by the institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator: 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.

Key Personnel: For purposes of this policy, "Key Personnel" will refer to CHS CIRB members, Investigators, Senior/Key Personnel and an investigator's immediate family; spouse, dependent children and a domestic or civil union partner.

Manage: taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Non-financial Conflict of Interest: A Non-financial Conflict of Interest will arise out of a CHS CIRB member's service in any of the following categories with respect to a research protocol under review:

a) Principal Investigator (PI)
b) Co-principal Investigator
c) Investigator receiving funding from the study, as listed in the study budget
d) Clinical Research Coordinator or research staff
e) A supervisory role over an investigator participating in the study
f) Participating or having a spouse, domestic partner or children participate in a study under review.

PD/PI: a project director or principal investigator of a research project; the PD/PI is included in the definitions of senior/key personnel and investigator.

PHS: the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH). PHS Awarding Component means the organizational unit of the OPHS that funds the research that is subject to this subpart, 42 CFR §50, Subpart F.

a) PHS funded studies: Institutions that apply for or receive research funding from PHS Awarding Components, including the National Institutes of Health for grants, cooperative agreements, and research contracts

Reimbursed Travel: travel for which the Key Personnel is paid back

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).

b) PHS definition of research includes: As used in the subpart, 42 CFR §50, Subpart F, the term includes any activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel: the PD/PI and any other person identified as senior/key personnel by the institution in the grant applications, progress report, or any other report submitted to the sponsor of the research.

Significant financial interest (SFI) Includes:

1. A financial interest consisting of one or more of the follow interests of the Personnel that reasonably appears to be related to their Institutional responsibilities:

    a) With regard to any publicly traded entity, a SFI 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 $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;

    b) With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds $5,000, or when the Personnel 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.

2. Key Personnel also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Key Personnel and not reimbursed to the Key Personnel 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, a qualifying 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 details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration.

Significant financial interest: Does <u>not</u> include:

1. Salaries, royalties, or other remuneration paid by the Institution to the Key Personnel if the Key Personnel is currently employed or otherwise appointed by the Institution;

2. Intellectual property rights assigned to the Institution 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 Key Personnel 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, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education; or

5. Income from service on advisory committees or review panels for a federal, state, or local government agency, a qualifying institution of higher education, an academic qualifying institution of higher education.

Sponsored Travel: Travel that is paid for on behalf of the Key Personnel, so that the exact monetary value may not be readily available.

Responsibilities of the Institution

1. Maintain an up-to-date, written, enforced policy on conflicts of interest that complies with 42 CFR §50, Subpart F and make the policy publically accessible.

2. Ensure that all Key Personnel receive education upon the initiation of the Institutions' policy on conflicts of interest and annually thereafter. The CHS CIRB will not review any protocols submitted for initial or continuing until all Key Personnel have submitted documentation of conflict of interest training and a completed Conflict of Interest Disclosure Statement if not completed within the prior twelve (12) months.

3. Ensure that those Key Personnel engaging in PHS-supported protocols complete the FCOI Training presented by the NIH Office of Extramural Research at: HTTP://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

4. Require that all Key Personnel complete a Conflict of Interest Disclosure Statement no less than annually. All Key Personnel will be required to complete an attestation that they have completed and/or updated a Financial Conflict of Interest Disclosure Statement with each submission for review or continuing review for all protocols.

5. A general statement will be printed on the meeting sign-in sheet at every CHS CIRB meeting reminding members of the conflict of interest policies and allowing any member to excuse himself from the deliberations of the committee. Their signature on the sign-in sheet will signify their agreement. No member of the CHS CIRB, investigator or consultant will be allowed to participate in the initial or continuing review of any protocol in which the member, investigator or consultant has a conflicting interest, financial or non-financial other than to provide information to the Board upon request and will be required to leave the room for the final deliberation and vote on that study.

6. CHS CIRB Meeting Minutes shall document the presence of any member, investigator or consultant with an identified conflict of interest along with their departure from the room during final deliberations and voting.

7. Research contracts or agreements, including payment schedules, will be reviewed by the research department prior to submission of the study for initial review, if possible. If this is not possible, the contract will be reviewed before final approval for initiation is granted.

8. Provide the sponsors with conflict of interest information as required by individual sponsor policy.

9. Provide external agencies, such as PHS, initial and ongoing reports of an investigator's FCOI . In addition, external funding agencies, such as PHS, obligate the Institution to make available to the public, upon request, information regarding FCOI's for Key Personnel.

Responsibilities of Key Personnel

1. All Key Personnel who have not completed Conflict of Interest education within the last four (4) years will complete the education prior to submitting a new protocol for initial review by the CHS CIRB.

2. All Key Personnel will complete a Conflict of Interest Disclosure Statement no less than annually and/or as new reportable interests are obtained. The forms will be maintained as confidential and will not be released except as required by Federal or state regulations.

3. All Key Personnel shall disclose any conflict of interest within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest. A Conflict of Interest Disclosure Statement may be obtained on the Internet and Intranet.

4. Key Personnel will complete an internal assessment of potential conflict of interest prior to submitting a protocol for initial or continuing review.

5. All Key Personnel shall disclose any conflict of interest on the Protocol Submission Form when requesting the initial review of the protocol.

6. All Key Personnel shall disclose any changes of conflict of interest on the Request to Renew a Research Study Form (if not done previously) when requesting the annual continuing review of the protocol.

7. Payments from a research sponsor to Key Personnel are prohibited if such payments are conditioned upon a particular research result or are tied to successful research outcomes.

8. Payments for subject enrollment or for referral of patients to research studies will be permitted only to the extent that such payments: are reasonably related to costs incurred, as specified in the research agreement between the sponsor, the investigator (s) and the Community Healthcare System; reflect the fair market value of services performed; and are commensurate with the efforts of the individual(s) performing the research.

9. If a CHS CIRB member is assigned as a reviewer for a protocol in which the individual has a conflict of interest, the Member shall notify the CHS CIRB office so that review of the protocol can be reassigned.

Noncompliance

Failure to report a significant financial interest may constitute professional misconduct and could be cause for disciplinary action. The following are examples of noncompliance with this policy:

a) Failure to submit a Conflict of Interest Disclosure Statement as required by this policy;

b.) Failure to submit a Conflict of Interest Disclosure Statement within 30 days of discovering or acquiring a new SFI;

c.) Submission of an incomplete, erroneous or misleading initial, updated or annual Conflict of Interest Disclosure Statement;

d.) Failure to complete Conflict of Interest education as required by this policy;

e.) Failure to comply with prescribed management plans.

Management of conflicts of interest

To evaluate reported conflict of interests:

a) Each Significant Financial Conflict of Interest and each Non-financial Conflict of Interest shall be presented to the CHS CIRB Chair and/or the Director of the CHS CIRB.

b) The CHS CIRB Chair and/or the Director of the CHS CIRB shall determine whether a potential conflict exists or can reasonably be construed to exist.

c) The CHS CIRB Chair and/or the Director of the CHS CIRB will report the potential conflict of interest to the Corporate Compliance Officer.

d) The Corporate Compliance Officer will review the protocol and any related contracts to determine if a conflict of interest exists.

e) Determine if the conflict of interest is related to a PHS funded study.

To manage reported conflicts of interest:

a) If it is determined that a conflict of interest exists:

i. The Corporate Compliance Officer will consult with the CHS CIRB Chair and the Director of the CHS CIRB to determine a course of action.
ii. All violations of federal or state statutes and guidelines shall be handled consistent with federal and state laws and requirements.
iii. The Key Personnel will be contacted to provide an explanation of the conflict of interest.

b) A plan to manage the conflict of interest will be determined and implemented within 60 days of identifying the conflict of interest. The plan may include, but is not limited to:
   i. Excluding the Key Personnel from participating in the deliberations and voting on protocols during CHS CIRB meetings;
   ii. Dismissal of the Key Personnel from the CHS CIRB membership;
   iii. Permitting a research study to proceed because the disclosed conflict is minimal and does not represent a possible source of unreasonable bias or an inappropriate activity;
   iv. Permitting a research study to proceed for full CHS CIRB review and approval with continued oversight and monitoring by the Corporate Compliance Officer where conditions have been imposed.
   v. Not permitting the research study to be conducted within the Community Healthcare System.
   vi. In the event that a conflict of interest affecting either the Key Personnel or the Community Healthcare System is identified for a study that is allowed to proceed, a Financial Interest Disclosure Addendum shall be added to the Investigational Consent document and any recruitment materials describing the conflict of interest.
   vii. In the case of PHS funded studies, reporting the conflict of interest to the awarding component.

c) Conditions that may be imposed by the CHS CIRB and/or the Corporate Compliance Officer may include but are not limited to:
   i. Public disclosure of FCOI when presenting or publishing the research;
   ii. Appointment of an independent monitor capable of taking measure to protect the design, conduct or reporting of the research against bias resulting from the FCOI;
   iii. Modification of the research plan;
   iv. Change of personnel and/or their responsibilities;
   v. Disqualification of personnel from participating in all or a portion of the research;
   vi. Reduction or elimination of the FCOI (sale of an equity interest);
   vii. Severance of relationships that create FCOIs.

d) The determination and the plan to manage the conflict of interest will be reported to the Key Personnel in writing by the Corporate Compliance Officer.

e) All documentation regarding conflict of interest will be maintained in the Corporate Compliance office for three (3) years after the date that the study was closed at the local site and the research budget has been reconciled.

Range of possible sanctions for noncompliance with this policy:

a) Written sanction;
b) Suspension of study;

c) Termination of study;
d) Suspension of research privileges;
e) Termination of research privileges;
f) Dismissal from CHS CIRB membership;
g) Violations of federal or state statutes and guidelines shall be handled consistent with federal and state laws and requirements;
h) Violations of this policy relating to participation in PHS funded projects shall be reported to the Awarding Component;
i) Violations of this policy that appear to have resulted in misrepresentation of research results or other unprofessional conduct will be handled according the CHS CIRB policies; IRB 3, Scientific Misconduct in Research and/or IRB 21, Non-Compliance/Complaint: Investigation of Allegations and Reporting

Key Personnel will have the right to appeal the sanction action to the Corporate Compliance Officer. This must be done in writing within 10 days of the notice of sanction.

Reporting Requirements to NIH for PHS Funded Studies

1. The Institution will submit an initial, annual and revised conflict of interest report to NIH;

    a) Prior to the expenditure of funds
    b) Within 60 days of identification of Key Personnel participating in a project;
    c) Within 60 days for new, or newly identified, conflicts of interest for existing Key Personnel;
    d) At least annually to provide the status of the conflict of interest and any changes to the management plan until the completion of the project;
    e) Following a retrospective review to update a previously submitted report;
    f) Regarding Key Personnel that fail to comply with the Institutions Conflict of Interest policy or a Management plan and the corrective action that was implemented;
    g) If bias is found with the design, conduct or reporting of NIH funded research which includes a Mitigation Report;

2. The Institution will access the Electronic Research Administration (eRA) from the NIH, Office of Extramural Research to submit the report electronically.

CROSS REFERENCE
Financial Conflict of Interest Disclosure Statement
Financial Interest Disclosure Addendum
IRB 3, Scientific Misconduct in Research
IRB 21, Non-Compliance/Complaint: Investigation of Allegations and Reporting
CFNI Policy: CC1.06 Conflict of Interest and Conflict of Interest Statement

REFERENCE:
45 CFR § 46.107: IRB Membership
21 CFR § 56.107: IRB Membership
42 CFR §50, Subpart F: Financial Conflict of Interest
45 CRR §94: Financial Conflict of Interest

ACCEPTED BY:

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Elizabeth Yee
Vice President, Clinical Ancillary Services

_____
Andrej Zajac, M.D
Chair, CHS CIRB

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Nancy Moser, RN, JD
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Jana L. Lacera, RN, MSA, CDM
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Director, IRB/Bio-Ethics

DATE REVISED 7/2012, 11/2017

REVIEWED BY: CHS CIRB January 2005, 6/2009, 9/2012, 6/2015, 1/2019, 2/2022
Institutional Legal Counsel Review February 2005
CFNI Board of Directors 7/20/05, 2012
MRF Board of Directors 8/23, 2005, 2012

Date	Initials
6/2009	JL
7/2012	JL
5/2015	JL
1/2019	JL
1/2022	JL