Policy Number	CIIACC 033
Title	Research Financial Conflict of Interest
Department/Division	CHRISTUS Institute for Innovation and Advanced Clinical Care
Owner	System Director of Research
Approvers	Dr. Bagchi, Pukar Ratti, Phyllis Everage, Francis Kanayo
Review Frequency	Every 3 years
Effective Date	October 1, 2016
Last Review Date	**July 2018**

Purpose

The purpose of this policy is to promote objectivity and protect the integrity of all research, including projects funded under Public Health Services (PHS) grants or cooperative agreements at CHRISTUS Health by minimizing or eliminating bias in the design, conduct, and reporting of research arising from real or apparent conflicting financial interest of a participating research investigator.

This policy also aims to provide guidance to PHS funded research investigators within CHRISTUS Health on how to correctly identify, promptly disclose, and adequately manage external commitments and financial interest that may adversely impact or appear to impact the PHS funded research. Investigators are responsible for disclosing their significant financial interests (SFI) as soon as they occur or are acquired.

Policy

A. Policy Statement

CHRISTUS Health is committed to complying with the requirements set forth in 42 CFR 50, Subpart F, for grants and cooperative research, and 45 CFR 94, for research contracts, in order to identify, evaluate, manage, and report to PHS all investigators' Significant Financial Interests (SFI) that may impact the objectivity and integrity of research conducted across all CHRISTUS Health regions.

B. Policy Application

This policy applies to all research investigators (including subgrantee/contractor/collaborating investigators and research personnel) who are involved in the design, conduct, or reporting of all funded research, especially PHS funded research, while performing human subject research related duties at or for CHRISTUS Health. This policy excludes applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

C. Guidance

1. Investigator responsibilities

Investigators shall disclose their SFIs or those of their family. All disclosures must be made to CIIACC via the iRIS portal along with all supporting documentation.

a. Annually: Each investigator who is engaged in funded research, including PHS funded research, must disclose SFIs to CIIACC at least annually, as long as the research grant lasts. This disclosure may include financial interests and updates that may not have been disclosed initially when the study began.

b. Event required basis: Investigators planning on undertaking a funded research, including PHS funded research, must disclose their SFIs no later than the time of application to the sponsor for funding.

c. New SFI: PHS funded investigator must disclose any new SFI to CIIACC within 30 days of discovery or acquisition (purchase, marriage, or inheritance). For non-PHS sponsored research, it is 90 days.
d. Other investigators: The principal investigator is responsible for providing the list of co/sub-investigators that are expected to comply with this policy.

2. Process for Reviewing Investigator Significant Financial Interests

The SO/D10 has delegated the obligation to perform the following to OHSRPP, under the direction of the System Director of Research on behalf of CHRISTUS Health;

Initial Review and Action

a. Solicit and review SFI disclosures from investigators and any pertinent information;
b. Make a determination as to whether a disclosed SFI is:
   i. Related to research; and
   ii. Constitutes an FCOI.

Note: An investigator's SFI is considered related to research when the SFI could reasonably affect the research or the SFI is in a non-CHRISTUS institution whose financial interests could be reasonably affected by the research.

c. Propose to the SO/D10 and the System VP Corporate Compliance-Privacy and the President of the CHRISTUS Health facility in question, on whether to prohibit or permit the external commitments and financial interest if there is a management plan to address the conflict.
d. Design a management plan commensurate with the FCOI in the event that the SO/D10 agrees to permit external commitments of the investigator. This allows the FCOI to be managed before and after IRB approval of research, and may require the investigator to provide additional information.

Note: If OHSRPP does not judge the external commitments to be FCOI, the external commitments may still be subject to administrative conditions.

i CHRISTUS Health Corporate Compliance ultimately oversees all FCOI and may modify FCOI management actions per System's current Conflict of Interest Policy.
ii. A copy of the final decision will be provided to the investigator, CHRISTUS Health IRB Chair and/or IRB of record, and the research compliance auditor within OHSRPP.

Investigator Appeal

e. Upon receipt of the decision, the investigator may either acknowledge it or submit an appeal.
f. An investigator may appeal the decision within 14 days of receipt of the final decision. The appeal may include; the specific items being challenged; reason for the appeal; justification for a different outcome and; an alternative management plan.
g. The appeal review and final determination shall be made by the SO/D10. Copies of final determination may be sent to the System VP Corporate Compliance-Privacy and the President of the CHRISTUS Health facility in question.

Institutional Remedies

h. Investigators are expected to comply with the final appeal determination. Failure to comply may result in investigators being subject to corrective action plans or other more stringent penalties like sanctions or denial of eligibility to engage in research.
i. Failure to comply with an FCOI management plan will trigger OHSRPP promptly notifying the PHS Awarding Component or other sponsor as required.

3. Management of Financial Conflict of Interest

a. Management plans shall be tailored to the investigator, the disclosed SFI, duration of the FCOI, and the research project in an effort to eliminate FCOI and promote transparency and research integrity.
b. Possible administrative conditions or restrictions that might be imposed include, but are not limited to:

Disclosure

I. Public disclosure of the FCOI during presentations or when publishing;
II. Disclosure to appropriate co-investigators and research group; or
III. Disclosure of the FCOI to enrolled research subjects via IRB approved consent forms.

Restriction of equity

IV. Placement of stock in escrow until a trigger date specified by OHSRPP; or
V. Prohibition of exercising options, warrants and similar instruments without prior permission.

Oversight

VI. Retaining the investigator on the research project but, appointing an independent monitor to ensure zero bias by reviewing abstracts or manuscripts before submission.

Protocol redesign

VII. Modification of the research plan

Limiting investigator role

VIII. Not allowing the investigator to; serve as a principal investigator; analyze data; determine subject eligibility; consent subjects; or clinically evaluate adverse events.
IX. Personnel changes or personnel disqualification

Divestiture

X Eliminating a financial interest that includes sale of an equity interest by a certain date.

Severance of relationship

XI. Severance of non-compliant relationships that may heighten or create actual or potential FCOI. Examples include terminating a consulting arrangement with an external commitment or relinquishing a seat on a board of directors.

c. PHS retains the right to request investigators to disclose FCOI in public presentations of results or create an addendum to previously published presentations of results if, an investigator did not disclose or did not manage FC0Is for PHS funded research.

d. PHS research with FC0Is will elicit ongoing monitoring of management plan until research completion.

4. New SFI during Active Research

In the course of a research study, a new SFI disclosure to OHSRPP will result in; review of the SFI; determination of relatedness to research; determination of whether FCOI exist; or development of a prescriptive management plan

5. Review of Existing SFIs and Retrospective Review during Active Research

a. Existing SFI Review: OHSRPP will make every effort to review all reported SFIs. If an existing SFI has not been previously reported or reviewed for PHS funded research, OHSRPP will review the SFI, make a determination, and develop a management plan within 60 days.

b. Retrospective SFI review: If an FCOI was not identified and managed adequately or an investigator failed to disclose SFI for an ongoing PHS funded research, within 120 days the OHSRP will perform a retrospective review of the investigator's activities and the PHS funded research to determine if any component of the research was biased in design, conduct, or reporting. The OHSRPP team will document the retrospective review in accordance with federal requirements set forth in 42 CFR 50.60(a) (3) (ii) (B) (1)-(9) for PHS funded research grants or cooperative agreements. OHSRPP will update the previously submitted FCOI report with the matching management plan.

c. Notification and Mitigation Report: In the event, OHSRPP finds bias in the design, conduct, and reporting of PHS funded research in a newly discovered FCOI, the research compliance auditor in conjunction with OSPRF will notify PHS Awarding component promptly, and submit a mitigation report as required by 42 CFR, Part §50.605(a)(3)(iii).

6. Training

All PHS funded research investigators will complete training on this SFI policy at the following times:

a. Prior to partaking in PHS funded research;
b. When new to CHRISTUS Health and willing to partake in an ongoing PHS funded research;
c. At least once every four years;

d. Immediately after major revision to this policy;
e. When a PHS funded investigator is not compliant with this policy by failure to disclose SFI or adhere to a FCOI management plan; and
f. At any time reasonably determined by the SO/D10.

Training may also be completed via CITI by selecting the Conflict of Interest Course.

7. Reporting of SFI for Sponsored Research including PHS Funded Research

a. OHSRPP, in conjunction with OSPRF, shall provide to PHS Awarding Component or other funding agency and non-PHS sponsors an FCOI report regarding any existing investigator FCOI along with a management plan. The report ("FCOI Report") to PHS will contain all the information required under federal regulations at 42 CFR §50.605(b) (3). Like C.5.a above, newly acquired FCOI for an ongoing PHS funded research shall be reported within 60 days.

b. Mitigation reports shall be promptly provided only to PHS Awarding Component per C.5.c above, if FCOIs that were not previously disclosed or managed for an ongoing PHS funded research and bias was found. Mitigation reports shall not be created for non-PHS Sponsors. The mitigation report shall include key elements documented in the retrospective review, including FCOI management plan. The PHS Awarding Component will consider the case and take appropriate steps to ensure objectivity in the PHS funded research. The required information includes:

I. Investigator's name, title, and role with respect to the research in question;
II. External entity's name where the financial conflict of interest is held;
III. Nature of the financial interest (equity, consulting fees, travel reimbursement, honorarium);
IV. Approximate dollar amount
V. Description of the relationship of the SFI to the PHS funded research and the basis for CHRISTUS Health determination that the SFI conflicts with research; and
VI. A description of the key elements of the management plan.

c. At the time of a research project extension, OHSRPP shall submit an annual FCOI report that delineates the status of an FCOI and changes to the management plan, if any, for the duration of the PHS funded research. Any request made by PHS will be shared with the CHRISTUS Health System Director of Research and the SO/D10.

d. To comply with federal regulations, OHSRPP will make available to the public, within 10 days of request, the following information with respect to the FCOI with PHS funded research:

I. Investigator's name, title and role with respect to research in question;
II. External entity's name where the financial conflict of interest is held;
III Nature of financial interest (equity, consulting fees, travel reimbursement, honorarium); and
IV. Approximate dollar amount

8. Records Retention

From the date the final expenditure is completed, the OHSRPP and OSPRF will retain for at least three (3) years records relating to investigator SFI disclosures and other pertinent information. Records may be kept longer if needed for litigation, audit, claim, or negotiation, or if other actions involving the records commences before the expiration of the three year period.

9. Public Accessibility

CIIACC will make available this policy on its website. PHS also requires that this policy be made available to the public upon request; information that would be disclosed are as listed in C.7.d above. CHRISTUS Health reserves the right to disclose or not disclose the management plan.

D. ADDENDUM

Addendum A - Definitions
Addendum B - Conflict of Interest Disclosure Statement Form

E. REFERENCES

1. Promoting Objectivity in Research. 42 CFR Part 50, Subpart F. Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is sought
2. Responsible Prospective Contractors 42 CFR Part 94.
3. Conflict of Interest Policy dated January 1, 2016.
4. Retrieved May 15, 2017. https://grants.nih.gov/grants/policy/coi/nih_review.htm

Approved By:

Pukar Ratti, MSChE, MSHCM, CHM, CCRP, FACMPE
System Director of Research

30 July 2018
Date

Sam Bagchi, MD
SVP, Clinical CMO-CMIO

8/14/18
Date

Definitions

ADDENDUM A

Administrative conditions: Are restrictions or sanctions that may be imposed by CHRISTUS research administration as a means to manage financial conflict of interests that may arise in funded research.

CHRISTUS Institute for Innovation and Advanced Clinical Care (CIIACC): A centralized management office for clinical research at CHRISTUS Health located at the CHRISTUS Health system office.

Design, Conduct, or Report of Research Oversight: Making decisions about or participating in research. This includes creating the structure, roles, and/or protocol of a research project, participating in the execution of the research roles and protocol, and participating in the publishing, presentation, or discussion of the research results.

Disclose: To provide pertinent information about an investigator's financial interests. Disclosure may entail informing parties inside and outside CHRISTUS Health in order to show full awareness of potential conflicts and institutional efforts to address them.

Equity: Refers to stocks, stock options, warrants, & other existing ownership interests in external commercial entity.
External Commitment: An obligation or activity (e.g., management, employment, advisory, or consulting role) that is
not related to primary commitments or obligations to CHRISTUS Health.
Examples of cases where external commitments might influence research include an entity that:

1. has products, services, or activities related to the areas of an investigator's research;
2. Funds research in an investigator's area of academic or clinical interest;
3. Owns or has rights to develop intellectual property that is the subject of research in which an investigator participates;
4. Competes commercially with such an entity as described in #3 above;
5. Makes or proposes to make a gift to CHRISTUS Health that would support an investigator's research work;
6. Furnishes products or services to CHRISTUS Health through a contractual process in which an investigator participates in any way;
7. Proposes to enter a licensing agreement with CHRISTUS Health with respect to technology invented by the investigator; or
8. Acts as a legal or de facto agent for any outside entity engaged in any of the above activities.

Family: An investigator's spouse, domestic partner or dependent children.

Financial Conflict of Interest (FCOI): A significant financial interest that could directly and significantly affect the design, conduct, or reporting of all research, including PHS-funded research.

1. A real FCOI arises when a financial interest, or other opportunity for personal financial gain, is likely to compromise or influence the objective, design, conduct, reporting, or direct administration of research.
2. An apparent FCOI arises when there is a reasonable appearance that an individual's opportunity for personal financial gain could compromise or influence the objective, design, conduct, reporting, or direct administration of research.

Investigator: The person who is independently charged with the design, conduct, or reporting of a funded research, including PHS funded research, on human subjects. This definition is independent of whether one is appointed or employed by CHRISTUS Health. Also referred to as principal investigator or investigator.

IRIS: Electronic portal of CHRISTUS Health IRB where investigators can report significant financial interest especially during submission of new research applications or continuing review applications.

Office of Human Subject Research Protection Program (OHSRPP): A department within CIIACC that consists of the CHRISTUS Health Institutional Review Board and Research Compliance (RC).

Office of Sponsored Programs and Research Finance (OSPRF): A department within CIIACC charged with managing all contracts and budgets of sponsored programs, including PHS funded research.

Public Health Service (PHS): Agencies within the Department of Health and Human Services (DHHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding component: The organizational unit of the PHS funds the research is awarded.

Research — a systematic investigation, including development, testing and evaluation designed to develop or contribute to generalizable knowledge. The term encompasses basic, sponsored, and clinical research, including applied research and product development

Research Compliance: An office within OHSRPP that manages all research compliance related issues.

Signatory Official or Designated Institutional Official (SO/D10): Vice President of Research and Academics at CHRISTUS Health

Significant Financial Interest (SFI): A financial interest consisting of one or more of an individual's and/or family's interests that reasonably appears to be related to an individual's CHRISTUS Heath research responsibilities:

1. With regard to any US or foreign publicly traded entity, a significant financial interest (SFI) 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, 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, etc.); 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, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when an individual or his or her family holds any equity interest (e.g. stock, stock option, or other ownership interest).

3. An SFI exist if related to intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

4. As required by the federal regulations and only for research personnel on PHS funded awards or cooperative agreements issued on or after August 24, 2012; SFI includes any travel that is reimbursed or paid on the individual's behalf, related to the individual's CHRISTUS Health responsibilities, and determined by CHRISTUS Health to constitute or contribute to an SFI. This excludes any travel that is reimbursed or sponsored by CHRISTUS Health, a federal, state, or local government agency, a U.S., non-profit 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.

The term significant financial interest (SF!) does not include the following:

- Salaries, royalties, or other remuneration paid by CHRISTUS Health to an individual, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights, if applicable;
- Equity interests or income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles;
- Remuneration from authorship of academic or scholarly works, regardless of the source;
- Income from seminars, lectures, or teaching engagements sponsored by, or income from service on advisory committees or review panels for, a federal, state, or local government agency, a non-profit U.S. 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; or

- Any paid for or reimbursed travel determined by CHRISTUS Health to not constitute an SFI

.

Sponsor: An external entity that funds or supports research. Sponsors include federal, state, and local governments and private entities, both nonprofit and for-profit.

System Director of Research: The Director of CIIACC at the CHRISTUS Health system office.

Small Business Innovation Research (SBIR) Program: The extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L.

ADDENDUM B

Principal investigators shall acknowledge and accept their responsibilities for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the IRS policies dealing with protection of human subjects, including:

- Federal wide Assurance of Protection of Human Subjects
- The Belmont Report
- The Code of Federal Regulations for the Protection of Human Subjects: Title 45 CFR Part 46; Title 21 CFR Parts 11, 54 54, 312, 314, 812, 814
- HIPAA Privacy Rules (45 CFR 160, 164)
- 1118 Policies and Procedures.

As such, PIs are responsible for obtaining CM certification every 3 years.

IL Principal Investigators certify that, before human subjects are involved in such research, proper consideration will be given ten

a) the risks to the subjects
b) the anticipated benefits to the subjects and others
c) the importance of the knowledge that may be reasonably expected to result
d) the informed consent process to be employed
e) the need for additional safeguards tithe human subjects are especially vulnerable
f) any alternative procedures or courses of treatment, if applicable
g) the subjects were consented using a language that is understandable and appropriate for their background and social standing

III. Principal Investigators who intend to involve human research subjects wilt not make the final determination of exemption from applicable Federal regulations or provisions. The investigator must submit a request for exemption, which will be reviewed by designated representatives of the IRS.

IV. Principal Investigators are responsible for obtaining and documenting informed consent in accordance with federal regulations (45 CFR Parts 46.116 and 48.117 and 21 CFR Parts 50.25 and 50.27) and CHRISTUS Health IRS policies.

V. Principal Investigators will promptly submit proposed changes in previously approved human subject research activities to the IRS. The proposed changes cannot be initiated without IRS review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

VI. Principal Investigators are responsible for submissions of annual progress reports of approved research to the IRS, which may be submitted at a frequency of less than one (1) year if the IRS so designates.

VI. Principal Investigators are responsible for submissions of annual progress reports of approved research to the IRS, which may be submitted at a frequency of less than one (1) year if the IRS so stipulates.

VII. Principal Investigators will promptly report to the IRS any serious adverse events (SAES) or other unanticipated problems involving risks to subjects or others in accordance with established policies.

VIII. Principal Investigators may provide emergency medical care to a patient without prior IRS review and approval, to the extent permitted by law and their scopes of licenses. Researchers vein affirmatively certify to full compliance with HIPAA and the use of patient Protected Health Information (PHI).

Conflict of Interest Disclosure Statement (ver 2.0)

I HAVE READ AND UNDERSTAND THE CHRISTUS RESEARCH FINANCIAL CONFLICT OF INTEREST POLICY

☐ Agree

The CHRISTUS Health System: Office of Human Subject Research Protection requires that each protocol submitted to the IRS for review must be
accompanied by a Conflict of Interest (COI) Disclosure Statement for each investigator/key personnel who is directly involved in the treatment or evaluation of research subjects in the covered study. COI Disclosure Statements must be completed, signed and submitted With the Initial IRS Application for review to occur.

In order to protect subjects from financial conflicts of interest or perceived conflict* of interest, the IRS requires that such potential conflicts be disclosed. If the IRS determines that a conflict exists that could influence the research or jeopardize the welt-being of subjects, the IRS may require additional information about the conflict or may require that the conflict be resolved before the research is approved. In addition, it may require that the conflict be disclosed to the subject in the Consent Statement.

If you or any member of your immediate family (spouse, children, parent, in--laws. and siblings) has a financial Interest In Other a public or private company whose drug, procedure, technique, device, or software Is used or tested in this study, please indicate the following:

I own equity in the company (stock ownership equal to or greater than 1% or $5,000, Stock Options, Real Estate, or other ownership interest in any amount) whose drug, procedure, technique, device, or software I am testing.

☐ Yes ☐ No

The Company holds patent rights to Inventions created by me or a member of my immediate family (spouse, children, parent, in-laws, and siblings).

☐ Yes ☐ No

*I or a member of my immediate family hold(s) a position of senior management officer, or director of the company whose drug, procedure, technique, device, or software I am testing.

☐ Yes ☐ No*

I am a scientific advisor or consultant to the company and I receive honoraria exceeding $5,000 annually,

☐ Yes ☐ N

*I am aware that if a device, technique, software, or procedure involved in the research is marketed, me or * member of me, immediate family will get royalty income or other income from the sale of the product.

☐ Yes ☐ No

· I have other financial interest that may appear to conflict with the protection of subjects or which should be disclosed to subjects in order to secure informed consent-

☐ Yes ☐ No

If a response to any of the above questions is YES, please include a separate explanation for any reported conflict of interest, and attach appropriate explanatory documents or information by clicking Application Summary at the top of this page and uploading the documentation on the Master Document Upload Section.

☐ Click here to access the text editor.

I acknowledge that I am required to notify the IRS within 10 business days if a cluing* in my disclosure status occurs.

Useful Websites

OHRP:http://www.hhs.gov/ohrp/

FDA: http//www.fda.gov/scienceResearch/SpecialTopics/RunningClinicalTrials/GuidanceInformationSheetsandNotices

HIPAA Privacy Rule: http://www.hhs.gov/

CHRISTUS Health Conflict of Interest Policy: https://christusservice-now.com/MyCHRISTUSLife/Knowledge/