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Financial Conflicts of Interest in Research

Purpose:

To ensure that Callen-Lorde Community Health Center staff who participate in research activities maintain the highest ethical standards and comply with Federal financial conflict of interest (FCOI) requirements (42 CFR 50, Subpart F), including disclosure of significant financial interests from all investigators, i.e. 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. Compliance with this policy will ensure the objectivity of research at Callen-Lorde and avoid actual or perceived conflict by defining the processes for identifying, reporting and managing conflict of interest. While the potential for conflicts of interest to arise in research is understandable due to the innovative and entrepreneurial pursuits of our research community, we must identify and manage situations in which financial or other personal interests could bias or compromise – or have the appearance of biasing or compromising – objectivity or judgment relative to research.

Scope:

This policy and procedure applies to all employees, contracted staff, interns, volunteers at Callen-Lorde Community Health Center and collaborators or consultants engaged in all activities meeting the definition of research at the center.

Definitions:

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Entity means an organization other than Callen-Lorde, whether public or private. Examples include the following: a company, partnership, professional association, voluntary organization etc

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

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

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

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.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or bio-specimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or bio-specimens; (ii) or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable bio-specimens.

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Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator'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 means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Key Personnel includes the PD/PI but also includes any other personnel that are considered to be “essential to work performance” on a project. Furthermore, Callen-Lorde defines Key Personnel on human subject protocols as Research personnel directly involved in conducting research specific interventions with study participants, or their private identifiable information (PII), or protected health information (PHI).

Manage means 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.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this sub-part.

PHS means 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 PHS that funds the research that is subject to this sub-part.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

Research means 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). As used in this sub-part, the term includes any such 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 means the 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 this sub-part.

Significant Financial Interest refers to an external financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator's Immediate Family Members) related to their Institutional Responsibilities, when combined for the 12 months preceding the disclosure date, from a single Entity:

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Nature of Significant Financial Interest	Disclosure Threshold
Remuneration, compensation, and/or other payments for services, e.g., consulting	Exceeds \$5,000
Equity interests in a publicly-traded entity	Exceeds \$5,000
Equity interests in a non-publicly-traded entity	\$0 / Any
Intellectual property rights and interests	Exceeds \$5,000
Sponsored or reimbursed travel (PHS funded researchers only)	Exceeds \$5,000

Significant Financial Interests do **NOT** include:

- (1) Salary, royalties or other remuneration paid by Callen-Lorde Community Health Center to the Investigator if the Investigator is currently employed or otherwise appointed by the Center;
- (2) Equity interests through investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- (3) 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;
- (4) 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 teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education;
or
- (5) Sponsored or reimbursed travel sponsored or paid 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.

Policy:

Callen-Lorde Investigators who submit applications for research funding to any federal or industry sponsors, or other sponsors that have conflict of interest requirements, and/or Investigators engaged in research involving human research participants, regardless of funding source, are subject to the training, disclosure, review, and management requirements of this Policy unless otherwise specified in this Policy. Investigators funded by the Public Health Service (PHS) and/or other agencies that abide by PHS COI regulations are subject to additional requirements as specified in this Policy.

Staff must also comply with all other Callen-Lorde Community Health Center's policies on conflict of interest.

(1) Training Requirements

Investigators involved in research at Callen-Lorde Community Health Center must complete required conflict of interest training before engaging in research and every four years thereafter and maintain up

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to date Human Subjects Research Ethics and Compliance Certification. Documentation of trainings must be submitted to their research supervisor or the Senior Director of Research and Education.

(2) Disclosure

Investigators are required to disclose any Significant Financial Interests that reasonably appear to be related to the Investigator's Institutional Responsibilities. For the purposes of this Policy, a Significant Financial Interest includes an external financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator's Immediate Family Members), related to their Institutional Responsibilities, when combined for the 12 months preceding the disclosure date, from a single Entity. Investigators must disclose Significant Financial Interests prior to engaging in research, within 30 days of discovery or acquisition of a new Significant Financial Interest, and at least annually during the annual Staff conflict of interest disclosure processes (even if acknowledging no change to previous disclosures). All new investigators are required to complete a Financial Disclosure Form within 30 days of hire. Individuals who become newly responsible for the design, conduct, reporting, or direct administration of research are required to complete a Financial Disclosure Form within 30 days of their assumption of such responsibilities. The Senior Director of Research and Education is responsible for soliciting and reviewing all Financial Disclosure Forms. These forms are maintained by The Research Department for at least three years from the date the final expenditure report is submitted for a research project or at least three years from the date the final report is submitted for a research project, whichever is longer.

Procedure:

Any significant Financial Interests that are disclosed will be reviewed by a FCOI team consisting of 3 members; the Executive Director, one member of Callen-Lorde's Finance Department, and one member of the Compliance & Risk Management Department. Conflict of interest reviews take into account the nature and extent of an Investigator's role on a project, the nature and extent of an Investigator's Significant Financial Interest(s), and the nature of the research activity under review. These reviews are conducted to assess whether or not Significant Financial Interests of an Investigator relate to and could directly and significantly affect the design, conduct, or reporting of research, thus presenting a Financial Conflict of Interest relative to the research, or an appearance thereof.

The FCOI team will perform an initial review of all Investigator disclosures of Significant Financial Interests relative to all applicable research projects. The FCOI team may make determinations, on a research project by research project basis, that an Investigator's Significant Financial Interests do not relate to nor have the ability to directly and significantly affect the design, conduct, or reporting of the research. Reviews and determinations must occur prior to expenditure of funds for new projects and within 60 days of newly-disclosed Significant Financial Interests. Additionally, reviews and determinations must occur within 60 days of the addition of new Investigators to projects during the life of a project.

(1) Management

If a Financial Conflict of Interest determination is made, the FCOI team must develop a conflict of interest management plan to manage, reduce, or eliminate the Financial Conflict of Interest. Conflict of interest management plans are strategies designed to mitigate the potential for an Investigator's

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Significant Financial Interests to impact or bias research objectivity and/or the safety or welfare of human research participants.

Conflict of interest management plans could include disclosure of the Financial Conflict of Interest (to study teams, collaborators, the Institutional Review Board, human research participants, and in presentations and publications), a reduced role in the research, and/or independent review of research data and results. Additional conflict of interest management strategies may be employed depending on the nature of the Financial Conflict of Interest and the nature of the research activity. In extreme cases, an Investigator may be prohibited from participating in research due to the level and extent of Significant Financial Interests deemed to present a Financial Conflict of Interest relative to specific research activity. Callen-Lorde will not permit an Investigator with an Financial Conflict of Interest that has not been sufficiently managed to conduct a clinical research protocol whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment in human subjects.

Investigators must acknowledge agreement to conflict of interest management plans in order to engage in research for which Financial Conflict of Interest determinations are made.

The FCOI team will notify the IRB of record about the Financial Conflict of Interest determinations made, and conflict of interest management strategies implemented.

The conditions of and compliance with Investigator conflict of interest management plans will be reviewed on at least an annual basis by FCOI team. On an ad hoc basis, the FCOI team can also conduct independent monitoring and verification to ensure that the conditions of conflict of interest management plans are being met.

(2) External Reporting

The FCOI team will provide initial and ongoing reports relative to Investigator's Financial Conflict of Interest determinations as they relate to specific research activities to the PHS and other research sponsors as required. For Financial Conflicts of Interests relative to PHS-funded research, the FCOI team must perform the required conflict of interest reporting prior to the expenditure of funds for new projects, within 60 days of newly-determined Financial Conflicts of Interest identified during the life of a project, and on an annual basis thereafter prior to progress report submission during the life of a project. The FCOI report will include:

- a) The name of the investigator with the FCOI
- b) The name of the entity with which the investigator has an FCOI
- c) The nature of the Significant Financial Interest
- d) The value of the financial interest
- e) Description of how the financial interest relates to the NIH-funded research and why the institution determined that the financial interest conflicts with such research
- f) Description of the key elements of the institution's management plan, including other required information

In addition, PHS requires Callen-Lorde to make available to the public, upon request, specific information regarding Financial Conflicts of Interest determined for senior and key personnel relative to

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PHS-funded research. The FCOI team is required to provide specific information relative to such public requests within five business days of the request.

(3) Subrecipients

Callen-Lorde Community Health Center must apply relevant originating sponsor conflict of interest requirements to subrecipients. Therefore, Callen-Lorde must identify whether or not a subrecipient has a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements. If a subrecipient does not have a conflict of interest policy compliant with applicable originating sponsor conflict of interest requirements, in order to proceed with any collaboration, the subrecipient must agree to abide by this Policy relative to the subrecipient investigators and the specific subrecipient research activity for the duration of that activity. The subrecipient agreement must incorporate terms that establish whether the conflict of interest policy of Callen-Lorde or that of the subrecipient will apply to subrecipient investigators, and obligations of the subrecipient relative to conflict of interest in either case.

(4) Noncompliance

The following are examples of noncompliance with this Policy:

- a) Failure to submit a timely disclosure;
- b) Submission of an incomplete, erroneous or misleading initial, updated or annual disclosure;
- c) Failure to disclose information as required by this Policy; or
- d) Failure to comply with prescribed management plans.

Any instances of Investigator noncompliance may require that the Investigator repeat required conflict of interest trainings. Ramifications for noncompliance could include restrictions relative to proposing and engaging in research and/or an internal review of the research, as well as other disciplinary action up to and including termination.

For instances of noncompliance involving PHS-funded research, whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including failure by the Investigator to disclose a Significant Financial Interest, or failure of an Investigator to comply with the conditions of a conflict of interest management plan, Callen-Lorde must conduct a retrospective review of the Investigator's research activities on the project to determine if there is bias in the design, conduct, or reporting of the research resulting from the Financial Conflict of Interest. The retrospective review must be completed within 120 days of the determination of noncompliance. If bias is found in the course of the retrospective review, Callen-Lorde must promptly notify PHS and submit a mitigation report that addresses the impact of the bias on the research and the plan of action to eliminate or mitigate the effect of the bias.

Additionally, for instances of noncompliance noted above involving PHS-funded clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Investigator is thereafter required to disclose the Financial Conflict of Interest in each public presentation of the results of the relevant research and also request an addendum to previously published presentations of the relevant research.

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(5) Confidentiality

Access to information collected in connection with this Policy will be limited to those with a need to know and will be shared in accordance with Callen-Lorde policies and federal regulations.

(6) Record Retention

Conflict of interest records relative to research covered under this Policy must be maintained for a period of three years after any applicable research project's final financial report is submitted to the sponsor, or until three years after the final action has been taken on any audit, litigation, or claim.

(7) Inquiries

All inquiries related to Callen-Lorde's Financial Conflict of Interest Policy or to obtain information on the Significant Financial Interests of senior/key personnel should be made to the Senior Director of Research and Education

Document Information

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