Lifespan Office of Research Administration	**Subject: Research Conflict of Interest Policy**	**File under: CCPM - 43 Also - ORA GEN 003**
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I. PURPOSE

Lifespan is committed to conducting its research in accordance with the highest professional and ethical standards. It is Lifespan's policy to preserve the integrity and quality of research at Lifespan and to maintain public trust in our scientific endeavors by minimizing actual or perceived conflicts of interest in the conduct of research.

Lifespan's goal is to ensure that there is a reasonable expectation that the design, conduct, or reporting of research will not be biased by any conflicting financial and/or non-financial interest of an investigator. This policy has been adopted to clarify Lifespan's requirements regarding research conflict of interest disclosure and management.

Lifespan has established the mechanisms listed below to identify, analyze, manage or eliminate, where necessary, real, potential, and/or perceived conflicts of interest that may be detrimental to the safety of our patients, the validity of our discoveries, and the reputation of Lifespan and its research staff.

Lifespan is required to incorporate the Public Health Service (PHS) regulation at 42 CFR Part 50, Subpart F (revised August 2011) for grants or cooperative agreements and 45 CFR Part 94 (revised August 2011) for research contracts; the National Science Foundation (NSF) regulations found in Section 510 of its Grant Policy Manual (July 2005); the regulations

contained in the Uniform Guidance, 2 CFR 200; and regulation 21 CFR Part 54 of the Federal Drug Administration (FDA).

In addition, Lifespan's Corporate Compliance Policies #46, "Interaction with Industry Representatives (Pharmaceutical, Medical, Device and Medical Supply Industries)", #09, "Conflicts of Interest" and #76 Clinical Conflict of Interest: Physician Disclosure and Patient Consent of Vendor Business Relationships, Lifespan's Materials Management Policy #150, "Institutional Purchasing: Conflict of Interest Guidelines" further describe Lifespan's position on conflicts of interest. It is the responsibility of the Investigator, and his/her staff, to read, understand, and complete appropriate training with regard to these corporate compliance policies.

It is the responsibility of an Investigator and his/her staff to be familiar with the regulations and this policy; to complete the required training on conflict of interest, no less than every four years and immediately when required; to disclose significant financial interests (SFIs) to Lifespan prior to submitting an application for funding and within 30 days of discovering or acquiring a new significant financial interest; and to comply with any management plan issued by the Lifespan Research Conflict of Interest Committee (LRCOIC) and retain documentation that demonstrates compliance.

II. APPLICABILITY

This policy applies to all persons, regardless of title or position, who are ***responsible*** for the design, conduct or reporting of research that is conducted under the auspices of Lifespan. Principal Investigators of each project are responsible for assisting Lifespan in determining who meets the definition of "Investigator" (see Section III, Definitions) and are accountable for filing conflict of interest disclosures for each investigator involved in a given research project.

III. DEFINITIONS

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

B. ***Significant financial interest*** (SFI) means:

1. 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) that reasonably appears to be related to the investigator's institutional responsibilities:

    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, 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., but not limited to, consulting fees,

honoraria, paid authorship, fees for participation in speakers' bureaus); 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 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); or

c. Intellectual property rights and interests (e.g., patents, copyrights), **upon receipt of income** related to such rights and interests (**Note:** $5,000 *de minimis* exception does not apply).

2. If PHS funded, Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is 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. 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 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.

3. The term SFI does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by Lifespan or its affiliates to the Investigator if the Investigator is currently employed or otherwise appointed by the Lifespan entity, including intellectual property rights assigned to the Lifespan entity and agreements to share in royalties related to such rights;
- income from 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;
- income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an 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
- income from service on advisory committees or review panels for a Federal, state, or local government agency, an 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.

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. ***Financial conflict of interest report*** is Lifespan's report of financial conflict of interest to a Public Health Service (PHS) awarding component.

E. ***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 that is conducted at Lifespan. The Principal Investigators of each sponsored project must determine which people meet the definition of "investigator" and are responsible for the filing of conflict of interest disclosures for each person.

F. ***Institutional Responsibilities*** means an investigator's professional responsibilities on behalf of Lifespan including teaching, research, administration, and clinical care.

G. ***Disclosure Reporting Forms*** are the forms by which investigators submit information about a significant financial interest to Lifespan.

H. ***Secondary Disclosure Form*** is completed upon the request of the Lifespan Research Conflict of Interest Committee (LRCOIC) to assist that committee in gathering further information about the disclosed SFI.

I. ***Transactional*** **or** ***Ad hoc*** *or Annual* reporting is when an investigator submits a disclosure reporting form. *Ad hoc* reporting occurs when a faculty member or investigator reports a new significant financial interest that has not been reported previously. *Transactional* reporting occurs when an investigator submits a sponsored research proposal and/or a submission to the IRB, IACUC or other research review committee. *Annual* reporting occurs at the discretion of the LRCOIC and may replace *Transactional* reporting with the appropriate documentation.

J. ***Lifespan Research Conflict of Interest Committee (LRCOIC)*** is the Lifespan entity that is responsible for reviewing disclosure reporting forms and secondary disclosure forms; the LRCOIC determines whether a significant financial interest is related to the investigator's research and whether it constitutes an FCOI. Once an FCOI has been identified, the LRCOIC recommends to the Senior Vice President for Research a management plan and mechanisms to implement and monitor the plan.

K. ***Reporting*** is a method of managing a real or apparent FCOI by means of the release of relevant information about a significant financial interest to parties outside the LRCOIC. It may include public disclosure of a faculty member or investigator's significant financial interest in relevant publications and presentations, disclosure to co-investigators, members of the laboratory and research group and students or trainees, and disclosure on human subject consent forms.

L. ***Responsible Administrator*** is the Administrative Director of the Office of Research Administration, as designated by the Senior Vice President and Chief Research Officer to manage the COI disclosure process and the LRCOIC.

M. ***Institutional Officer (or Designated Official)*** is the Senior Vice President for Research who has overall responsibility for the Lifespan research program and who chairs the LRCOIC.

N. ***PHS*** means the Public Health Service of the U.S. Department of Health and Human Services, which includes, among other agencies, the National Institutes of Health (NIH).

O. ***Senior/Key Personnel*** means the Project Director/Principal Investigator and any other person identified as senior/key personnel by Lifespan in a grant application, progress report, or any other report submitted to the PHS by Lifespan.

IV. RESPONSIBILITIES AND DISCLOSURE OF CONFLICTS OF INTEREST

At the time a grant application is submitted through the Office of Research Administration (ORA)/Grants and Contracts, or a request for review by a Lifespan research review committee is made through ORA/Research Protections Office, the Principal Investigator (PI) must ensure that all Investigators (those personnel involved in the proposed project, who are responsible for the design, conduct or reporting of the research), disclose any significant financial interest (SFI), or certify that they have no such SFI.

The disclosure reporting form is part of the overall research review committee and/or grant application packet, which is reviewed and signed by the Chief of Service or Chairperson of the Department. For research projects that span more than one year, the disclosure process must be repeated annually.

In addition to the initial disclosure, an updated disclosure must be made any time in the course of an on-going research project that a new SFI is discovered or acquired (e.g., through purchase, marriage, or inheritance) by an investigator. Such updated disclosures must be made promptly (or within thirty (30) days for PHS funded Investigators) of discovering or acquiring the new interest. In order to ensure that any new SFIs are identified, a disclosure reporting form must be submitted when a grant transfers to Lifespan from another institution or a new investigator is hired. Other changes to existing disclosures that do not constitute "new" SFIs must be included at the time of annual disclosure.

If a disclosure form indicates that an SFI exists, the investigator must obtain signature by the Chief of Service or Chairperson of the Department, on the disclosure form, indicating that they have discussed the disclosed SFI with the researcher. **Where SFIs are disclosed, no research may proceed until the LRCOIC has determined whether a financial conflict of interest (FCOI) exists and, if it does, has established and implemented a financial conflict of interest management plan**.

When the investigator indicates that s/he has an SFI the information is communicated to the Responsible Administrator, who contacts the investigator for additional information via a secondary disclosure form (Part II) The information requested is more specific than the identification of the SFI, including questions regarding the specific amounts of the SFI and the investigator's suggestions for reducing bias in the study, if necessary. This information is forwarded to the LRCOIC for their deliberations.

In the case that an Investigator is reviewed on an annual basis, rather than on a transactional basis, the Investigator will complete and submit the secondary disclosure form (Part II) at least annually.

V. LIFESPAN RESEARCH CONFLICT OF INTEREST COMMITTEE

The Lifespan Research Conflict of Interest Committee (LRCOIC) was formed to review SFI disclosures made by investigators engaged in research at Lifespan or any of its hospitals and to seek additional information and make recommendations as necessary.

The LRCOIC is a subcommittee of the Lifespan Executive Corporate Compliance Committee (ECCC), reporting annually or more frequently if necessary. The ECCC reports to the Lifespan President and CEO. The members of the LRCOIC are appointed by the Chair of the ECCC. The committee is comprised of senior members of Lifespan's research community and Lifespan administration, and may include persons such as the Senior Vice President for Research serving as the Chairperson, Chiefs/Chairs, a member of the General Counsel's Office, the VP of Internal Audit and Compliance, the Administrative Director of the Office of Research Administration; and representative researchers from Lifespan's affiliates.

The objective of the LRCOIC is to manage, reduce or eliminate the real, potential and perceived risks of conflicts to the institution, research patients and the integrity of the research results.

Committee meetings will be scheduled with notice, and minutes will be taken. A simple quorum of the appointed members will be necessary to conduct business. Copies of the minutes, disclosure forms and other pertinent information will be kept in a secure and confidential manner for at least five years, after the termination or completion of the project to which they pertain or resolution of any civil, government or internal actions involving the records, whichever is later.

In addition, the LRCOIC committee will consider instances of non-financial conflict of interest in their deliberations. A non-financial conflict of interest may exist when an individual serves dual roles, such as health care provider and investigator. Other interests such as publication, promotion, or tenure can also become conflicts of interest that may affect an individual's judgment. Membership in oversight committees such as the IRB, as well as positions of authority, may pose potential conflicts of interest.

A. Responsibilities of the LRCOIC:

The LRCOIC will conduct its evaluation in confidence and with the goal of protecting research subjects, researchers and Lifespan.

The primary responsibilities of the LRCOIC are as follows:

1. Review SFI disclosure statements submitted by investigators and key personnel on sponsored research applications; or projects utilizing any one of Lifespan's research review committees; or through an annual reporting process. Such review may also include review of the relevant research plans, subject consent forms, and other case-specific financial information.

2. Determine whether a disclosed SFI is related to an investigator's Lifespan research. An SFI is related to an investigator's Lifespan research when Lifespan reasonably determines that the SFI could be affected by the research; or is in an entity whose financial interest could be affected by the research.

3. Determine whether a disclosed SFI that is related to an investigator's research is an FCOI, and if so, whether the FCOI requires a management plan or elimination. An FCOI exists when the LRCOIC reasonably determines that an SFI that is related to an investigator's research could directly and significantly affect the design, conduct, or reporting of the research. Any FCOI must be managed by the Institution before a grant can be activated and/or before the research project may commence.

4. For PHS-funded research, review and determine if disclosures of sponsored or reimbursed travel are related to an investigator's research and, if so, whether they constitute an FCOI.

5. If an FCOI is identified, develop an FCOI management plan and monitor on an ongoing basis.

6. Review regularly and revise periodically as necessary research conflict of interest policies and procedures.

7. Review and consider the impact of institutional conflict of interest on proposed research

B. <u>Management Considerations for the LRCOIC:</u>

In the event the LRCOIC identifies an FCOI, the LRCOIC will consider it in the context of this policy, the Public Health Service (PHS) regulations, if applicable, the Lifespan Corporate policies and any other applicable standards.

As this is a case-specific process, there is no one formula that dictates which management actions best resolve an identified FCOI. The Committee will keep the following in mind as it develops its' management plans:

- Relationship of the investigator(s) to the entity that is the source of the SFI
- Magnitude of the financial interest
- Nature of the research project and role of the investigator(s)
- Relative value of the technology to the entity that is the source of the SFI

- Risks to the research subjects (i.e., invasive, non-invasive; multi-center, single center trial)

C. Potential Management Actions by the LRCOIC:

The Committee will take actions designed to manage any identified FCOI to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

These actions may include, but are not limited to:

For the Investigator:

- Modification of the research plan;
- Disclosure in all relevant presentations and publications;
- Disclosure to research subjects through the human subject consent forms (see Appendix 1);
- Disclosure in all internal presentations to students and fellows and other internal presentations;
- Reduction or elimination of the financial interest(s) that create conflicts (e.g., divestiture or reduction of an equity or other financial interest, placing into escrow stock and financial payments for a specific time frame, restricting stock options from being exercised without the prior permission of Lifespan);
- Severance of outside relationships that create conflicts; and
- In some cases the conflicted investigator may not serve as PI, may not obtain consent from research subjects, may not analyze data, and/or may otherwise be required to limit his/her participation in a study.

Additional Oversight of Research:

An institutional or departmental oversight committee may be formed to review the research both while in progress and through data preparation, publication and reporting. The oversight committee will report to the LRCOIC as required in the management plan. External consultants or advisors may be used in this role.

D. Disapproval of the Research:

The LRCOIC may recommend disapproval of a particular research relationship and/or project if an identified FCOI cannot be managed or reduced. Regardless of whether a research review committee (e.g., Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), or the DNA Committee) has already given approval, the LRCOIC may, through its disapproval of a project, cause the project to be withdrawn and or the relationship to be terminated. If an investigator proposes to use human subjects in research for which an FCOI has been identified, a convened IRB shall be given the opportunity to review, comment upon, and ultimately to approve the LRCOIC management plan. If the IRB feels that human subjects will not be protected by the LRCOIC management plan and there are no amendments to the plan that would change that conclusion, it may

recommend, at a convened meeting, disapproval of the plan in which case the research may not proceed. The IRB Chair, or designee, will communicate such a decision to the LRCOIC.

E. Notification of Committee Action

The Committee's written management plan for an identified FCOI will be made available to the investigator and or key personnel involved, and, if applicable, to the President of Lifespan affiliate(s) involved, the Chairman of the Department, the Office of Research Administration and the Executive Corporate Compliance Committee. Investigators subject to the management plan will be required to acknowledge in writing their acceptance of the plan.

If applicable, the Chair of the Institutional Review Board (IRB) and/or the Institutional Animal Care and Use Committee (IACUC) will also be notified of the LRCOIC's actions.

F. Additional Actions by the Committee:

When a disclosed interest is determined not to constitute one that the LRCOIC is charged with reviewing (e.g., it does not meet the definition of an SFI, or it is found not to relate to the investigator's institutional responsibilities) or a disclosed interest is reviewed by the LRCOIC and is determined not to be an FCOI, the Responsible Administrator may nonetheless determine that some types of management or oversight of the interest are appropriate before certain research activities may proceed. Lifespan, through the LRCOIC, may develop additional procedures and/or guidance regarding these types of interests and any associated limitations or requirements.

G. Continuous Review:

All FCOI management plans will be reviewed per the terms of the plan, but no less than annually. Investigator compliance with the terms of any FCOI management plan will be monitored on an on-going basis until the completion of the research.

The LRCOIC will review, with the ECCC, its process annually.

VI. REQUIRED CONFLICT OF INTEREST TRAINING

Each investigator is required to complete conflict of interest training prior to engaging in any research and at least every four years. The training will cover the Lifespan conflict of interest policy, the PHS regulations applicable to conflicts of interest, and the specific disclosure obligations on Lifespan investigators. Additional training will be required on an immediate basis (or no later than 60 days if PHS funded), if Lifespan revises its conflict of interest policy in a way that affects the requirements applicable to investigators, when an investigator is new to Lifespan, or when an investigator fails to comply with this policy or an imposed FCOI management plan.

VII. INVESTIGATOR NONCOMPLIANCE

The protection of research subjects and the viability of the peer-reviewed conflict of interest program at Lifespan depend on complete and accurate disclosure(s) of information by the investigators required by the disclosure forms. Failure to disclose this information and to comply with all aspects of this policy breaks the first link of public trust, and will result in sanctions by Lifespan and/or the researchers' academic/service departments. Failure by investigators to adhere faithfully to the terms of a management plan imposed by the LRCOIC undermines the system that permits research in which an FCOI has been identified to proceed responsibly and safely, and such failure will also result in sanctions by Lifespan and/or the researchers' academic/service departments. Such sanctions may include, but are not limited to: termination of employment, suspension or termination of research privileges, termination of the research project, suspension, reprimand or other such remedial actions.

VIII. CONSIDERATION OF STUDENTS AND SUBORDINATES

To limit potential conflicts of interests and to protect the relationship of educator/mentor and students or subordinates, researchers may not solicit for personal benefit gratuities, favors or anything of monetary value from subordinate staff, matriculating graduate students, undergraduate students, medical students, or post-doctoral fellows. Additionally, researchers must inform subordinates of any financial interests they might have in research in which the subordinate will be involved. Researchers may not personally invest or own stock in privately held business ventures of their subordinate staff, matriculating graduate, undergraduate, medical students or post-doctoral fellows, under their supervision. Students should only be involved in Lifespan research that positively benefits the students and their academic requirements.

IX. PHS-SPECIFIC REQUIREMENTS

A. **General:** *This section describes additional FCOI requirements that are specific to PHS-funded research and that affect Lifespan as a grantee organization; it will be updated as Federal regulations mandate.*

For PHS sponsored research, prior to expenditure of any funds under the award, Lifespan must reasonably determine whether any SFI or travel disclosed by any investigator is related to the proposed project; if so, whether it can reasonably be determined that the SFI constitutes an FCOI; and if an FCOI is determined to exist, how the FCOI will be managed or eliminated, and how the management plan will be monitored. An investigator's SFI is related to PHS-funded research when Lifespan reasonably determines that the SFI could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the PHS-funded research. Lifespan may involve the relevant investigator in the determination of whether an SFI is related to the PHS-funded research.

For all PHS awards, prior to expenditure of any funds under the award, Lifespan is required to report to the PHS Awarding Component the existence of an FCOI and submit an FCOI report. The report must contain:

- The project number, name of investigator with the FCOI, nature of the financial interest (e.g., equity, consulting fee, etc.), name of the entity with which the investigator has the FCOI, the project director (PD)/principal investigator (PI) or the contact PD/PI if a multiple PD/PI model is used, and the value of the financial interest (provided in dollar ranges);

- A description of how the financial interest relates to the PHS-funded research and the basis for the determination that the financial interest conflicts with the research;

- A description of the key elements of the management plan, including:

    - The role and principal duties of the conflicted investigator in the research project;

    - Conditions of the management plan;

    - How the management plan is designed to safeguard objectivity in the research project;

    - Confirmation of the investigator's agreement to the management plan; and

    - How the management plan will be monitored to ensure investigator compliance.

Lifespan is responsible for submitting FCOI reports to NIH initially (prior to expenditure of funds) and annually during the award period, and within 60 days of any subsequently identified FCOI. Additionally, if the failure of an Investigator to comply with this policy or an FCOI management plan appears to have biased the design, conduct or reporting of the PHS-funded Research, Lifespan shall promptly notify the PHS awarding agency of the corrective action taken or to be taken.

B. <u>Subrecipient or Subcontractor:</u>

When proposed Lifespan research is to be carried out through a subrecipient, Lifespan will establish in writing, at the time of proposal submission, whether Lifespan's conflict of interest policy or that of the subrecipient will apply to the subrecipient's investigators, as well as the time frames within which the subrecipient must provide any information necessary to ensure that Lifespan is able to meet its reporting obligations to the PHS Awarding Component.

C. <u>Sponsored or Reimbursed Travel:</u>

On an <u>annual basis</u>, investigators with PHS awards are required to report to the Responsible Administrator of Lifespan the occurrence of any reimbursed travel or "sponsored" travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), that reasonably appears to be related to their institutional responsibilities *except* when travel is reimbursed by:

- A federal, state, or local government agency;

- An institution of higher education as defined at 20 U.S.C. 1001(a);
- An academic teaching hospital;
- A medical center; or
- A research institution that is affiliated with an institution of higher education.

Investigators must provide information on the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Lifespan may determine that additional information is necessary to determine whether certain sponsored or reimbursed travel constitutes an FCOI. Investigators must provide in a timely manner any additional information requested by Lifespan regarding disclosed travel.

D. Public Accessibility:

Lifespan will ensure public accessibility of information concerning the FCOIs of senior/key personnel subject to this policy. Prior to Lifespan's expenditure of any funds under a PHS-funded research project, Lifespan will, upon receipt of a written request for information to the Responsible Administrator, provide a written response within five (5) business days regarding any SFI disclosed and still held by the senior/key personnel that has been determined to relate to the PHS-funded research and constitute an FCOI pursuant to this policy.

The information to be provided in the response will include:

- The investigator's name, title, and role with respect to the research project;
- Name of the entity in which the significant financial interest is held;
- Nature of the significant financial interest;
- Approximate dollar value (provided in dollar ranges) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

E. New Interests that Arise During an On-Going PHS-Funded Research Project

To the extent a new SFI is disclosed to Lifespan in the course of an on-going PHS-funded research project (i.e., an investigator who is new to participating in the research discloses an SFI or an existing Investigator discloses a new SFI), or Lifespan identifies an SFI that was not previously reviewed in a timely manner by Lifespan in accordance with this policy, the Responsible Administrator will, within (60) days from the date of the disclosure: (i) determine if the SFI relates to the Investigator's research; (ii) if it relates, determine if it qualifies as an FCOI; and (iii) if it is an FCOI, implement on at least an interim basis a management plan in accordance with this policy. The Responsible Administrator may, depending on the circumstances of the SFI, conclude that additional interim measures are necessary with regard to the Investigator's participation in the research between the date of disclosure or identification and the completion of the Responsible Administrator's review (including, where warranted, a retrospective review as discussed below).

F. Retrospective Review, Identification of Bias and Mitigation Reporting

In the event of failure to meet PHS regulations, including failure by the investigator to disclose timely an SFI that is determined by the LRCOIC to constitute an FCOI; Lifespan's failure to review or manage such an FCOI; or investigator failure to comply with a FCOI management plan, Lifespan is required, within 120 days of its determination of noncompliance, to complete a retrospective review of the investigator's activities and the PHS-funded research project to determine any bias in the design, conduct or reporting of research during the time period of the noncompliance.

Lifespan will document at least the following information regarding any retrospective review:

- Project number.
- Project title.
- 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 FCOI.
- 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.
- Conclusions of the review.

If bias is found, Lifespan will notify PHS, develop and implement a mitigation plan, and submit the PHS-required mitigation report, which will include at least the elements documented in the retrospective review (see above) and a description of the impact of the bias on the research project and Lifespan's plan of action or actions taken to eliminate or mitigate the effect of the bias. Any FCOI report submitted to the PHS Awarding Component with respect to such research will be updated as necessary in light of the results of the retrospective review.

In any case in which the department of Health and Human Services (HHS) determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical deice, or treatment has been designed, conducted, or reported by an investigator with an FCOI that was not managed or reported by Lifespan in accordance with applicable PHS regulations, Lifespan will require the investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

G. Record Retention:

Federal regulations mandate that for research contracts each Institution maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for three years after the final payment, or where applicable, for the other time periods specified in 48 CFR Part 4, Subpart 4.7.

For grants and cooperative agreements, the Institution must maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable from other dates specified in 45 CFR 74.53 (b) for different situations.

Note that Lifespan may retain records longer than required by Federal regulations.

X. PROCEDURAL STATEMENT

If a Lifespan Employee or a Lifespan Professional Staff member has a *question concerning* the *interpretation or applicability* to a particular circumstance of any of the laws or regulations referred to in this Policy, such Lifespan Employee or Lifespan Professional Staff member should first consult with his/her supervisor(s) and if his/her supervisor(s) is unable to answer the question or provide any guidance or, if, because of the circumstances, it would be inappropriate to discuss the matter with his/her supervisor(s), then such Lifespan Employee or Lifespan Professional Staff member should contact either the Lifespan Office of Research Administration, Office of the General Counsel or the Corporate Compliance Officer for advice. If any Lifespan Employee or Lifespan Professional Staff member is aware of any violation or threatened or potential violation of this Policy, or *suspects* a violation of this Policy has occurred, such Lifespan Employee or Professional Staff member should contact the Lifespan Compliance Officer.

No adverse action will be taken against any party who reports, in good faith, any violation or apparent or threatened violation of this policy.

Appendix 1: Conflict of Interest Model Language for Research Subject Consent Form

Generic Disclosure

The person leading this medical research study might benefit financially from this study. The Institutional Review Board and a committee at Lifespan or its Affiliate have reviewed the possibility of financial benefit. They believe that the possible financial benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

Specific Disclosure

The person leading this medical study might benefit financially from this study. [***Specifically, insert appropriate description from below]***. The Institutional Review Board and a committee at Lifespan or its Affiliate have reviewed the possibility of financial benefit. They believe that the possible financial benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

Descriptions

The relevant description below should be inserted into the above disclosure if requested by the Lifespan Research Conflict of Interest Committee.

Salary support

Company XYZ is paying some or all of the salary for the doctors and staff who are working this research study.

Money Received Outside of the Study

This research study is supported by money from Company XYZ. In addition, the person leading this research study receives extra money from Company XYZ for work that is not a part of this study. These activities may include consulting, advisory boards, giving speeches, or writing reports. The person running this research might receive hundreds or thousands of dollars for this work.

Researcher Holds a Patent

The person leading this medical research study owns [or has applied for] a patent on the new [test, drug, treatment] being studied. Research studies like the one you are thinking about joining are done to determine whether the new [test, drug, treatment] is safe and effective. If research shows the new [test, drug, treatment] is safe and effective, the person leading this study would receive a part of the profits from any sales of this [test, drug, treatment]

Lifespan or its Affiliate Holds a Patent

Research studies like the one you are thinking about joining are done to determine whether the new [test, drug, treatment] is safe and effective. Lifespan or its Affiliate

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Researcher Owns Equity

This research study is designed to test a product made by Company XYZ. The person running this study has an investment in Company XYZ, such as stock. The amount of money this investment is worth might be affected by the results of this study. This means that the person running this study could gain or lose money depending on the results of this study.

University Owns Equity

This research study is designed to test a product made by Company XYZ. Lifespan or its Affiliate has an investment in Company XYZ, such as stock. The financial value of this investment might be affected by the results of this study. This means that Lifespan could gain or lose money depending on the results of this study.