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Project Name:	Quality Management System
Document Title:	Financial Conflict of Interest (FCOI) Policy

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Document Approvals

Role	Name	Signature	Date



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Revision History

Revision	Issue Date	Changes
A0	July 30, 2015	First revision of the procedure that governs the Company FCOI policy for Siloam Biosciences.

1 DOCUMENT OVERVIEW

1.1 Purpose

This document defines the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of Siloam Biosciences research and to comply with federal regulations.

1.2 Scope

This procedure addresses the specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulation. Promoting Objectivity in Research (45CFR part 94-Responsible Prospective Contractors). This regulation was developed to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of research funded under National Institutes of Health (NIH) agreements will be free from bias resulting from Investigator financial conflicts of interest.

1.3 Definitions

The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of FCOI. A complete list of definitions can be found at 45CFR94.3

1.3.1 Institution

An institution is any domestic or foreign, public or private, entity or organization applying for or receiving NIH research funding.

1.3.2 Investigator/ Principal Investigator

The principal investigator and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research funded by the NIH. The Principal Investigator (PI) will be identified in the contract proposal and contract.

1.3.3 Financial Interest

Anything of monetary value, whether or not the value is readily determined

1.3.4 Financial Conflict of Interest (FCOI)

An FCOI is a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

1.3.5 Significant Financial Interest (SFI)

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:

(i) 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 (ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, 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 (iii) upon receipt of income related to intellectual property rights and interests (e.g. patents, copyrights)

(2) 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, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by the Company directly (i.e. the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip, identify of the payer/sponsor, destination and duration. The Company is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes a FCI with NIH-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests:

(i) salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution; (ii) intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; (iii) any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; (iv) 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;

(v) 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 (vi) income from service on advisory committees or review panels for a federal, state or local government agency, 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.

1.4 References

1.4.1 External References

[E1] 45CFR94 FCOI-Responsible Prospective Contractors

[E2] FCOI training course: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

1.4.2 Internal References

Table-1: Internal References

No.	Document ID	Title
[I1]	QMS-0-QP-00XX-A0	Significant Financial Interest Disclosure Form

1.4.3 Attachments

No Attachments.

1.5 Associated Documents

Table-4: Associated Documents

S. No.	Document ID	Title
1	QMS-0-QP-00XX-A0	Significant Financial Interest Disclosure Form

2 RESPONSIBILITIES

- 2.1. It shall be the responsibility of the Principal Investigator of a Research project to inform each investigator on this policy on financial conflicts of interest and to require each investigator to complete training [E2] and sign a conflict of interest form (1).
- 2.2. It shall be the responsibility of the Principal Investigator identify all Investigators who have a SFI requiring disclosure
- 2.3. It shall be the responsibility of all investigator(s) of an NIH funded project to go through training [E2]
- 2.4. The Vice President or Principal Investigator is responsible to track SFI's and report any changes.

3 PROCEDURE

3.1. The NHI Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest. Siloam Biosciences requires for any investigators involved with an NIH funded project to complete this tutorial and print a completed certificate.

This course is accessible at

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

3.1.1. Upon completion of the training, a certificate of completion must be turned into the Principal Investigator or Vice President. This training is required prior to participating in any research relating to any NIH funded grant or contract or as deemed necessary by Siloam Biosciences or the NIH. This includes investigators new to the company or when there are changes in the FCOI policy.

3.1.2. Training must be completed prior to submission of each proposal and at least every four years and immediately when the procedure is revised, a new investigator joins the project or if an investigator is found not to be in compliance.

3.2. Upon completion of the tutorial and before any NIH proposal is submitted, any Significant Financial Interests (SFI) as defined above shall be disclosed on the Significant Financial Interest Disclosure Form (1).

3.3. All investigators listed on any NIH Funded research proposal will fill out and sign a Significant Financial Interest Disclosure form. Regardless of whether an SFI exists, all investigators are required to submit an SFI Disclosure form with each proposal.

3.4. If there is an SFI reported the investigator must fill out Part II of the form for each Significant Financial Interest reported.

3.5. New disclosure forms will be submitted with each contract or when an SFI change occurs.

3.6. Submission and Review of Significant Financial Interest Disclosure Form - Every individual having a SFI requiring disclosure under this policy shall prepare a fully-completed SFI Disclosure Form that shall be submitted to the Vice President. An initial review of the SFI Disclosure Form will be conducted by the Vice President to determine whether a potential for conflict of interest exists. If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the SFI identified in the SFI Disclosure Form. A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests;
 - Review of research protocols by independent reviewers;
 - Monitoring of research by independent reviewers;
 - Modification of research plan;
 - Disqualification from participation in all or a portion of the research funded;
 - Divestiture of significant financial interests;
 - Severance of relationships that create actual or potential conflicts
- . Compliance of the management plan shall be monitored by the Vice President.

3.6.1. All management plans are required to be signed by the Principal Investigator and the Vice President. Compliance of the management plan shall be monitored by the President.

3.6.2. Violations of Conflict of Interest Policy – Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the Vice President shall make recommendations to the President regarding the impositions of sanctions or disciplinary proceedings against the violating individual.

3.6.2.1. In addition, the Company shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved.

3.5.3 Initial report – prior to the Company’s expenditure of any funds under a NIH-funded research project, the Company must provide to the NIH an FCOI report regarding any Investigator SFI found by the Company to be a financial conflict of interest in accordance with the regulation.

3.5.4. During on-going NIH-funded research projects – the Company shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, the Company shall submit a FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.

3.5.5 Annual FCOI report – For any FCOI previously reported to the NIH, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

3.6. If there is no FCOI to be reported, no report will be issued.