Financial Conflicts of Interest - updated to include the 2011 revised FCOI regulation, promoting objectivity in research (42 CFR Part 50 Subpart F)

NIH requires grantees and investigators to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is sought." That subpart promotes objectivity in research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will not be biased by any conflicting financial interest of an investigator. The signature of the Authorized Organizational Representative on the face page of the application serves as certification of compliance with the requirements of 42 CFR Part 50, Subpart F. Under the requirements the organization will do the following:

-Have an up-to-date, written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought.
-Shall promote and enforce Investigator compliance with the regulations.
-Shall manage FCOI and provide initial and ongoing FCOI reports.
-Agrees to make FCOI and SFI information available to HHS, promptly, upon request.
-Before spending any NIH funds awarded under a new award, inform the CGMO of the existence of any conflicting financial interests it identified of the type covered by 42 CFR 50.605.
-When informing the CGMO that a financial conflict of interest has been identified, ensure that the interest has been addressed in accordance with the regulations by indicating whether the conflict has either been managed, reduced, or eliminated.
-Continue to make similar reports on subsequently identified conflicts within 60 days of identifying them.
-Make additional information available to NIH, upon request, as to how it handled conflicting interests in accordance with the regulations.

Aronora's Training Requirements
Each Investigator will be informed, through the distribution of Aronora's Policies and Procedures Manual, of Aronora's FCOI policy as well as the Investigator's disclosure responsibilities, which mirror the Federal regulation (42 CFR 50.604 (b)). FCOI training will be required for all Investigators 1) prior to engaging in research related to any PHS-funded grant, 2) at least every four years or 3) immediately, if Aronora revises its FCOI policy that affects the Investigator requirements, investigator is new to the Institution, or if an Investigator is not in compliance with the plan. To complete the training, each Investigator will review this document along with the following webinars and tutorials provided through the US Dept. of Health & Human Services OER http://grants.nih.gov/grants/policy/coi/index.htm :

-Financial Conflict of Interest Presentation with Case Studies (06/26/2012)
http://grants.nih.gov/grants/policy/coi/FCOI_NIH_Regional_Seminar-June_22_2012.ppt
-Web based tutorial
http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm
-NIH FCOI Reporting Requirements and eRA Commons FCOI Module Demonstration:
http://grants.nih.gov/grants/policy/coi/fcoi_webinar_2012/FCOI%208-14-2012_WEBINAR.pdf
-Summary Slide Set for the revised 2011 FCOI Regulation (10/05/2011)
http://grants.nih.gov/grants/policy/coi/FCOI.ppt

All Investigators at Aronora must sign a letter stating that they have reviewed and agree to abide by all FCOI requirements.

Disclosure, Review and Monitoring Requirements
Each Investigator is required to disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meets the regulatory definition of SFI: 1) no later than at the time of application for PHS-funded research, 2) At least annually during the period of award, 3) within 30 days of discovering or acquiring a new SFI. The 2011 revised regulation that guides Aronora's policy defines a "Significant Financial Interest" as follows:

> "(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. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(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) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(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 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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."

The revised 2011 regulation does not apply to Phase I SBIR/STTR applications but the revised 2011 regulation does apply to Phase II SBIR/STTR applications/awards. As defined in Section 50.603 Definitions, a "Significant Financial Interest" does not include "….any ownership interest in the [applicant or awardee] Institution held by the Investigator, if the Institution is a commercial or for-profit organization;…". Therefore, the Investigator's equity interest is excluded from the disclosure requirement when the for-profit company is the Institution that is applying for, or that receives, the PHS research funding in which the Investigator is participating.

The designated institutional official will solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities. The institutional official will determine, using the above guidelines, whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI. The designated official will review all Investigator SFI disclosures, determine if any SFIs relate to PHS-funded research, determine if an FCOI exists (SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research), develop and implement management plans, as needed to manage FCOIs. The designated official will review disclosures of SFIs, make determination of FCOIs, and implement a management plan when required for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a

new SFI. The designated official will review disclosures of SFIs, make determination of FCOIs, and implement a management plan within sixty days whenever an Institution identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution. The designated official will take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.
The President is currently designated as the institutional official, and is responsible for ensuring the proper collection and reporting of all FCOIs according to the above guidelines.

Q: What must an Investigator disclose for his/her first financial disclosure under the 2011 revised regulation related to intellectual property rights and interests?
Upon the receipt of income, the Investigator is required to disclose the aggregated value of income received in excess of $5,000 from the entity in the twelve months preceding the disclosure. Because this income is subject to the definition of "Significant Financial Interest," the following disclosure considerations apply:
(1) Investigators who are planning to participate in PHS-funded research must disclose their SFIs over the previous twelve-month period to their Institution no later than at the time of application for PHS-funded research.
(2) Each Investigator who is participating in PHS-funded research must submit an updated disclosure of SFIs at least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.
(3) Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFIs within 30 days of discovering or acquiring a new SFI.

Reporting Requirements to NIH
The designated institutional official will send initial, annual (i.e., ongoing) and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for the Institution and its subrecipients, if applicable, as required by the regulation: 1) prior to the expenditure of funds, 2) within 60 days of identification for an Investigator who is newly participating in the project, 3) within 60 days for new, or newly identified , FCOIs for existing Investigators, 4) at least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extention) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project, 5) following a retrospective review to update a previously submitted report, if appropriate. The designated institutional official will notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report in accordance with and including all reporting elements as required by the regulation 42 CFR 50.605(a)(3)(iii). The designated institutional official will notify NIH promptly if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research. Aronora will notify NIH promptly and take corrective action for noncompliance with the policy or the management plan.

All FCOI reports will contain a description of the key elements of Aronora's management plan including the following:
(A) The role and principal duties of the conflicted Investigator in the research project;
(B) Conditions of the management plan;
(C) How the management plan is designed to safeguard objectivity in the research project;
(D) Confirmation of the Investigator's agreement to the management plan;
(E) How the management plan will be monitored to ensure Investigator compliance; and
(F) Other information as needed.

Updated or annual FCOI reports will include the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted to the NIH.

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE		
REPORT	**CONTENT**	**REQUIRED WHEN?**

New FCOI Report (Initial submission	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	(1) Prior to expenditure of funds (2) Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year progress report, or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	When bias is found as a result of a retrospective review.

Q: How should the FCOI report be submitted to NIH?
For awarded grants and cooperative agreements, Institutions must submit all FCOI reports to the NIH through the electronic Research Administration (eRA) Commons FCOI Module. See NIH Guide for Grants and Contracts, Notice No. NOT-OD-09-072.

Maintenance of Records
Aronora will maintain all FCOI-related records for at least 3 years from the date the final expenditures report is submitted to the PHS (NIH).

Enforcement Mechanisms and Remedies and Noncompliance
Sanctions or other administrative actions to ensure Investigator compliance will be fully implemented depending on the nature and severity of the noncompliance. These sanctions may include anything from a written warning to termination of employment. The designated institutional official will complete and document retrospective reviews within 120 days of the Institution's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation. In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to: 1) Disclose the FCOI in each public presentation of the results of the research, and 2) to request an addendum to previously published presentations.

Subrecipient Requirements
When applicable, a written agreement will be implemented that states the subrecipient will follow the FCOI policy of the awardee Institution. If applicable, Aronora will obtain a certification from subrecipient(s) that its FCOI policy complies with the regulation. If applicable, this will include a written subrecipient agreement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the awardee Institution to

report identified FCOIs to the NIH as required by the regulation. Alternatively, if applicable, included in the written agreement will be a requirement to solicit and review subrecipient Investigator disclosures so as to enable the awardee Institution to identify, manage and report identified FCOIs to the NIH.

Public Accessibility Requirements

Aronora agrees to post this FCOI policy on its public Web site, or if there is no current presence on a publicly accessible Web site, and only in those cases, make FCOI policy available within 5 business days of a request. If a presence on a publicly accessible Web site is acquired, post FCOI policy within 30 days. Aronora will also make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), publicly accessible prior to the expenditure of funds. The information will: 1) Include the minimum elements as provided in the regulation, 2) Be posted on a Public Website or made available within 5 calendar days of a written request, 3) Be updated, at least annually (Web site only but any response to a written request should include the updated information), 4) Be updated, within 60 days of a newly identified FCOI (Web site only but any response to a written request should include the updated information), 5) Remain available for three years from the date the information was most recently updated.

The information that the Institution makes available via a publicly accessible Web site or written response shall include, at a minimum, the following:

i. Investigator's name;

ii. Investigator's title and role with respect to the research project;

iii. Name of the entity in which the Significant Financial Interest is held;

iv. Nature of the Significant Financial Interest; and

v. Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) 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.

PDF DOWNLOAD OF THIS DOCUMENT:
Aronora's FCOI Policy