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SECTION:	Human Resources	NUMBER:	3.3
SUBJECT:	Financial Conflict of Interest	REVISION:	V2
		EFFECTIVE DATE:	August 24, 2012

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## Financial Conflict of Interest Policy

### **PURPOSE**

InterveXion Therapeutics (“InterveXion”) is committed to maintaining objectivity in research. These standards are established to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded by NIH grants, cooperative agreements or contracts will be biased by any conflicting financial interest of an Investigator. InterveXion will abide by the federal regulations as put forth in 42 CFR Part 50 Subpart F.

### **SCOPE**

This policy applies to all InterveXion personnel, whether members, managers or employees, that seek PHS funding as an Investigator on an InterveXion grant application.

### **DEFINITIONS**

1. **Designated Official(s):** Unless otherwise specified, the Designated Official functions will be split between the Director of UAMS BioVentures (“Outside Review Manager”) and a committee of all InterveXion Managers less the Investigator of interest (“Internal FCOI Review Committee”).
2. **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.
3. **Internal FCOI Manager:** Unless otherwise specified, InterveXion’s Operations Director or equivalent full-time position will assume the role of Internal FCOI Manager.
4. **Investigator:** The Principal Investigator **and** any other person who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding.

**Significant Financial Interest (SFI):** 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:

- With regard to any publicly traded entity, an 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); 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.

- 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 the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 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 InterveXion 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.
  - Initial disclosures of sponsored travel must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

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

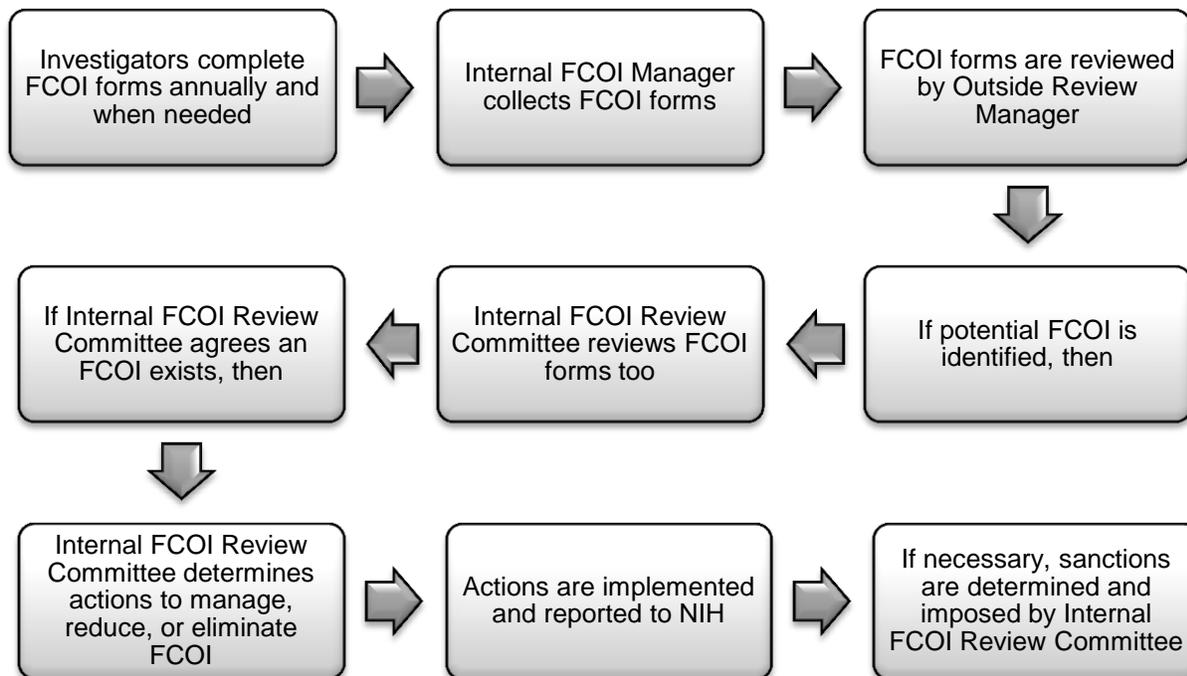
- salary, royalties, or other remuneration paid by InterveXion to the Investigator if the Investigator is currently employed or otherwise appointed by InterveXion, including intellectual property rights assigned to InterveXion and agreements to share in royalties related to such rights.
- any ownership interest in InterveXion held by the Investigator.
- 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.
- 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.

## **POLICY**

InterveXion members, managers and employees must demonstrate professional loyalty to the company and its research and business pursuits. When outside activities and/or business relationships interfere with perceived loyalty, these must be disclosed as described in this policy to ensure that potential financial conflicts of interests are identified, managed, reduced, or eliminated.

***A financial conflict of interest exists when the Designated Officials reasonably determine that a Significant Financial Interest that is related to the PHS-funded research could directly and significantly affect the design, conduct, or reporting of that research.***

The following procedure will be followed to ensure that FCOIs are identified, managed, reduced, or eliminated. The procedure and individual responsibilities are detailed in the text below the diagram.



### TRAINING

1. It is InterveXion's policy that Investigators be trained on the company policy concerning FCOI, the Investigator's disclosure responsibilities and the applicable Federal regulation.
2. Investigators will be trained on the following occasions:
  - Prior to engaging in research related to any PHS-funded grant
  - At least every four years, and
  - Immediately if:
    - InterveXion revises the FCOI policy to affect the requirements of Investigators,
    - An Investigator is newly employed by the company, and
    - An Investigator is not in compliance with the policy or implemented management plan.
3. Investigator training may be conducted by oral review of this policy by phone or in person, and will be confirmed by trainee and trainer signatures at the end of the policy.

### INVESTIGATOR RESPONSIBILITIES

1. **Disclosure:** InterveXion Investigators are required to disclose to the Designated Official(s) a listing of SFIs (and those of his/her spouse and dependent children) that (1) would reasonably appear to be affected by the research for which PHS funding is sought, and (2) in entities whose financial interests would reasonably appear to be affected by the research. Disclosures will be made on an annual basis, or within 30 days of discovering or acquiring a new Significant Financial Interest, using either the FCOI Form A or B attached.

2. **Updates:** Prior to submission of a new PHS grant application (within the previous two months), involved Investigators are required to either confirm their status is unchanged using FCOI Form B (attached), or submit an updated disclosure.

### **INSTITUTIONAL RESPONSIBILITIES**

InterveXion will comply with the regulations in 42 CFR Part 50 Subpart F for grants and 45 CFR Part 94 for contracts ("Regulation").

The **Internal FCOI Manager** will be responsible for the following:

1. Training each Investigator on InterveXion's Financial Conflict of Interest Policy and obtaining their signature on a copy as evidence of agreement and intention to comply;
2. Collecting annual and updated disclosure statements from each Investigator;
3. Submitting disclosure statements for review to the Outside Review Manager;
4. Keeping all records as follows:
  - For at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 74.53(b) and 92.42(b).
  - Records include all Investigator disclosures of financial interests, InterveXion's review of and response to such disclosures and all actions under this policy or retrospective review.

Before InterveXion spends any funds under a new award or within 60 days of identification of a new FCOI, the Internal FCOI Manager will be responsible for:

1. Confirming that either 1) the Outside Review Manager and/or the Internal FCOI Review Committee have not identified any FCOIs, or 2) that management plans are implemented for all identified FCOIs.
2. Reporting to the PHS the existence of any FCOIs (unless identified and eliminated prior to expenditure of PHS funds) and assurance that InterveXion has implemented a management plan in accordance with the Regulation;
  - Reports are to be made to the PHS awarding component via eRA Commons online.
  - The report should include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. At a minimum, it should include the following information:
    - Grant or Contract number, as appropriate;
    - Principal Investigator (PI) or contact PI if the grant/contract is awarded under the multiple PI model;
    - Name of the Investigator (if different from the PI) with the FCOI;
    - Name of the entity with which the Investigator has a financial conflict of interest; Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
    - Value of the 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;
- A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- A description of the key elements of the Institution's management plan, including:
  - 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;
  - How the management plan will be monitored to ensure Investigator compliance; and
  - Other information as needed.

Subsequent to the initial report, the Internal FCOI Manager will be responsible for submission of an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. InterveXion will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

The **Outside Review Manager** will be responsible for the following:

1. Reviewing all SFI disclosures;
2. Determining if an SFI is a potential FCOI. To be an FCOI, the SFI must be:
  - Related to PHS funded research. An SFI is related to the PHS funded research if it can be reasonably determined that the SFI: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research, and
  - A financial conflict of interest exists if it can be reasonably determined that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
3. Suggesting potential action(s) to be taken by InterveXion to manage, reduce, or eliminate such FCOI.

If a potential FCOI is identified by the Outside Review Manager, the **Internal FCOI Review Committee** will be responsible for the following within 60 days of the disclosure:

1. Performing their own evaluation to determine whether they agree that a FCOI truly does exist. An FCOI exists when the Designated Officials reasonably determine that a Significant Financial Interest that is related to PHS-funded research could directly and significantly affect the design, conduct, or reporting of that research;

2. Specifying what actions will be taken by InterveXion to manage, reduce, or eliminate an FCOI identified by the Outside Review Manager. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:
  - public disclosure of SFIs;
  - monitoring of research by independent reviewers;
  - modification of the research plan;
  - change in personnel or responsibilities, or disqualification from participation in all or a portion of the research funded by the PHS;
  - divestiture of SFIs; or
  - severance of relationships that create actual or potential conflicts.
3. Developing a management plan for any managed FCOIs;
4. Implementing the specified actions in the management plan within 60 days of identification of the conflict;
5. Monitoring the Investigator for compliance with the management plan. If a determination of noncompliance is made, a retroactive review will be performed as detailed in the Special Cases section, 3 Retroactive Review.

#### **PUBLIC ACCESSIBILITY**

1. InterveXion will make this policy publicly accessible by posting on the InterveXion website.
2. If so requested, InterveXion will make available by written response within 5 business days, the following information concerning an SFI that is disclosed and still held by the senior/key personnel identified in official grant correspondence, that has been determined to be related to PHS-funded research, and that has been determined to be an FCOI:
  - the Investigator's name
  - the Investigator's title and role with respect to the research project
  - the name of the entity in which the significant financial interest is held
  - the nature of the significant financial interest; and
  - the 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.
3. The written response will note that the information is current as of the date of communication and subject to updates that should be subsequently requested by the requestor.
4. This information will remain available to the public for at least three years following the most recent update.

### SPECIAL CASES

1. **Subawards:** When carrying out PHS-funded research through subrecipients (e.g., contractors, collaborators) or subcontractors, InterveXion must ensure by writing (i.e., in the subaward contract) that Investigators working for such entities comply with the regulation, either:
  - by requiring the Investigators to comply with InterveXion's policy, or
  - by requiring the entity(s) to certify to InterveXion that they are compliant with 42 CFR Part 50 Subpart F, for grants and 45 CFR Part 94, for contracts.

In either case, the written agreement must specify the time period for subrecipient reporting any FCOI or Investigator disclosures to InterveXion.

InterveXion will also provide FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

2. **Compliance Failure:** In the event InterveXion determines that an Investigator participating in PHS funded research has failed to comply with this policy, the **Internal FCOI Review Committee** will within 60 days review and determine if a related SFI constitutes an FCOI. If an FCOI is identified, the committee will implement a management plan and in addition complete a retroactive review (see next paragraph). The **Internal FCOI Manager** will promptly notify the PHS by reporting the corrective action taken or to be taken.
3. **Retroactive Review:** In the case of non-compliance (i.e., 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 that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan), InterveXion will within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Such retrospective review will be documented and include at least the following information:
  - 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 financial conflict of interest;
  - 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; and
  - Conclusions of the review.

If appropriate based on the review, InterveXion will update any submitted reports and follow the requirements outlined in 42 CFR 50.605.

If bias is found, InterveXion will notify the PHS awarding component immediately and submit a mitigation report. InterveXion will comply with any further actions specified by the PHS awarding component.

4. **Clinical Research:** In any case in which the HHS determines that an PHS-funded 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 a conflicting interest that was not disclosed or managed as required by the regulation, InterveXion will require the Investigator(s) involved to:
- disclose the conflicting interest in each public presentation of the results of the research, and
  - to request an addendum to previously published presentations.

### **SANCTIONS**

Failure to disclose conflicts of interest in an appropriate and timely manner or failure to comply with procedures to resolve conflicts of interest as implemented by the Internal FCOI Review Committee will result in administrative sanctions as determined by the Internal FCOI Review Committee.

Administrative sanctions may include, but are not limited to:

- Oral admonishment;
- Written reprimand;
- Reassignment;
- Disqualification from submitting proposals for research support to Federal agencies or other sponsors;
- Demotion;
- Suspension; or
- Separation.

### **APPEAL**

Appeal of any determination or sanctions imposed may be made to the Outside Review Manager, whose decision will be final and binding and not subject to further appeal.

### **ACKNOWLEDGEMENT AND AGREEMENT**

The undersigned Investigator acknowledges that he/she has been trained on and agrees to comply with InterveXion's Financial Conflict of Interest policy as stated herein:

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

The undersigned trainer acknowledges that he/she has trained the above named Investigator who has agreed to comply with InterveXion's Financial Conflict of Interest policy as stated herein:

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

SECTION: Human Resources  
SUBJECT: Financial Conflict of Interest, Form A

NUMBER: 3.3  
REVISION: V2  
EFFECTIVE DATE: August 24, 2012

Financial Conflict of Interest  
Form A

Name: \_\_\_\_\_

Position: \_\_\_\_\_

Date: \_\_\_\_\_

Type of disclosure:     First Time Form     Annual Update     Ad Hoc report

To comply with Federal and InterveXion policies on Financial Conflict of Interest (FCOI), disclosure of relevant Significant Financial Interest is required of all Investigators responsible for the design, conduct, or reporting of PHS-funded research, or proposed for such funding. The definition includes the Investigator’s spouse and dependent children. Significant Financial Interest is defined in InterveXion’s FCOI policy.

For the following questions, only report those situations that are related to your responsibilities on an InterveXion grant and, to an outside person could appear to affect objectivity in the PHS-funded research conducted at InterveXion.

To complete the tables, you may add lines if necessary.

- 1. With regard to any publicly traded entity, have you or your immediate family received remuneration over the preceeding 12 months or hold any equity interest in the entity that 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

Yes     No

If yes, provide details of these interests in the following table:

Business Name and Address	Type of Business	Description of Interest	Held by Whom	Value of Interest/ Remuneration

2. With regard to any non-publicly traded entity, have you or your immediate family received over the past 12 months remuneration which when aggregated, exceeds \$5,000, or do you or a family member hold any equity interest (e.g., stock, stock option, or other ownership interest)?

Yes     No

If yes, provide details of these interests in the following table:

Business Name and Address	Type of Business	Description of Interest	Held by Whom	Value of Interest/ Remuneration

3. Do you or your immediate family hold intellectual property rights and interests (e.g., patents, copyrights) and expect to receive income related to such rights and interests (e.g., licensing fees or royalties)?

Yes     No

If yes, describe the intellectual property rights and interests with enough detail for a reviewer to determine if it is related to any InterveXion PHS-funded research and if so, if the rights and interest are a financial conflict of interest. More information may be requested if necessary.

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4. Have you or your immediate family been the recipient of reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator (or family member) and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their InterveXion responsibilities? This disclosure 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.

Yes     No

If yes, provide details of the sponsored travel in the following table:

Purpose of trip	Sponsor/Organizer	Destination	Duration of trip

**Declaration:**

I, \_\_\_\_\_, declare that this statement of Significant Financial Interests has been examined by me and to the best of my knowledge and belief is a true, correct and complete statement of all my significant interests as required by Federal regulations in 42 CFR Part 50 Subpart F for grants and 45 CFR Part 94 for contracts. I have read and agree to abide by InterveXion's Financial Conflict of Interest policy and procedures. I understand that the policy states that failure to file this statement in a timely manner or intentionally filing a false statement may result in disciplinary action. Any changes to this statement will be reported when the information becomes known to me.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Date received by Internal FCOI Manager: \_\_\_\_\_

Internal FCOI Manager name and title: \_\_\_\_\_

SECTION: Human Resources  
SUBJECT: Financial Conflict of Interest, Form B

NUMBER: 3.3  
REVISION: V2  
EFFECTIVE DATE: August 24, 2012

Financial Conflict of Interest  
Form B

I, \_\_\_\_\_, declare that no changes to my reported Significant Financial Interests have occurred since my last financial conflict of interest disclosure.

Date of last disclosure: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Date received by Internal FCOI Manager: \_\_\_\_\_

Internal FCOI Manager name and title: \_\_\_\_\_