

Financial Conflict of Interest Policy

Covered Institution:

Orbital Research Inc., “Company” or “Institution” is covered under this policy as required by the National Institutes of Health (NIH) and applicable US. regulations. It is the responsibility of the Company to Promote Objectivity in all Research performed by or for the company including all research for which Public Health Service, which includes the National Institutes of Health, funding is sought or obtained. Significant Financial Interest (SFI)s include financial interests that are related to an Investigator’s institutional responsibilities. The Company is responsible for determining whether SFI relates to NIH-funded research and if it is a Financial Conflict of Interest (FCOI).

This Policy provides the standards that provide a reasonable expectation that the design, conduct, and reporting of NIH-funded research will be free from bias resulting from Investigator financial conflicts of interest. The Company shall maintain an up-to-date, written, enforced policy that complies with the FCOI regulation and make available via a publicly accessible Web site. The Company and all of its employees shall comply with this Policy and applicable regulations in all research.

Purpose:

This regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. It applies to any SFI [as defined below] that could directly and significantly affect the design, conduct, or reporting of company research, including NIH-or other Government funded research. This Policy does not apply to Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Phase I applications and grants.

HHS/NIH Authority:

The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in NIH-funded research. The NIH and the Department of Health and Human Services (HHS) have authority that applies before, during, or after an award with regard to any Investigator disclosure of financial interests, regardless of whether or not the disclosure resulted in the Institution’s determination of an FCOI.

Applicable Regulations:

- 42 CFR Part 50 Subpart F (grants and cooperative agreements)
- 45 CFR Part 94 (contracts)
 - Initial Regulation effective 10-1-95
 - http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm
 - Revised Final Rule published on 8-25-11
 - <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

Definitions:

Company shall mean Orbital Research Inc.

Institution shall mean Orbital Research Inc.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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

Responsible Individual shall mean that person designated herein.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation. (Note: Different definition than the NIH Grants Policy Statement.)

Significant Financial Interest (SFI) shall be interpreted as:

(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 excluded sources provided in regulation.

The following shall be **excluded** from Significant Financial Interest:

1. Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
2. Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights;

3. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
4. 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;
5. 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
6. 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.

Publication of FCOI Policy and Conflicts:

This Policy shall be made available in the “About Us” Section of the Company’s publically assessable web site. It shall be updated as required when changes are made or as specified in the regulation. Additionally, prior to the expenditure of any NIH/HHS funds, the Responsible Individual shall make information concerning FCOIs held by senior/key personnel via the Company’s Web site in the “About Us” Section, and update such information as specified in the regulation.

Training:

FCOI training required. Each Investigator must complete training prior to engaging in research related to any NIH-funded grant and at least every four years, and immediately under the designated circumstances:

FCOI training is required of each Investigator:

- Prior to engaging in research related to any NIH funded project;
- At least every four years, and
- Immediately when any of the following circumstances apply:
 - (i) Institution revises its policy in a manner that affects the investigator;
 - (ii) When an investigator is new to the institution; or
 - (iii) When the institution finds an Investigator is not in compliance with the Institution’s policy or management plan.
- The training must inform each Investigator of the:
 - (i) Regulation;
 - (ii) Institution’s policy on FCOI; and
 - (iii) Investigator’s responsibilities regarding disclosure of SFIs

Duties of the Investigators:

- Participate in Training and understand this Policy.
- Complete required forms in a timely manner.
- Monitor Subrecipients’ Investigators
- Take necessary actions to eliminate or mitigate FCOIs of the Investigator’s programs.

- Incorporate language as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators and include a time period to meet disclosure requirements, if applicable, and FCOI reporting requirements to the awardee Institution.
 - ❑ Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS/NIH Awarding Component (i.e., to NIH through the eRA Commons FCOI Module) to meet FCOI reporting obligations.

Investigator Disclosure of SFI:

The investigator shall disclose any SFI:

- **At time of Application:** Require that each Investigator, including subrecipient Investigators, if applicable, planning to participate in PHS/NIH-funded research to disclose to the designated official(s) at time of application.
- **Annually:** Require each Investigator, including subrecipient Investigator, if applicable, to submit an updated disclosure of SFI at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award.
- **Within 30 days:** Require each Investigator, including subrecipient Investigator, if applicable, who is participating in the NIH-funded research to submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Duties of the Responsible Individual:

- Take necessary actions to manage FCOIs of the Company's Investigators, including those of subrecipient Investigators
- Train Investigators and Company employees in the Policy
- Document training
- Obtain required documents from Investigators including disclosures at time of application, annually, and within 30 days of discovering a SFI
- Maintain Records
- Communicate SFIs and FCOIs with the President
- Communicate with the NIH
- Monitor compliance
- Conduct an audit not less than every two years of contracts to subrecipients to for FCOI language. Document the audit findings.
- If an Institution identifies an SFI that was not disclosed or reviewed in a timely manner, the Responsible Individual shall within sixty (60) days review the SFI in coordination with the President, determine if an FCOI exists and implement an interim management plan, if needed.
- In cases of non-compliance, complete a retrospective review and submit a Mitigation Report if bias is found.

Management Plan:

Any FCOI or non-compliance with this Policy shall be reported to the Responsible Individual. The Responsible Individual shall determine if there was a non-compliance in coordination with the President. The Responsible Individual shall within 120 days of the Institution's determination of non-compliance,

complete a retrospective review of the investigator's activities and the NIH-funded research project to determine if there was bias in the design, conduct, or reporting of such research. The Responsible Individual shall document the retrospective review.

If bias is found, a Mitigation Report shall be prepared by the Responsible Individual.

The retrospective review and Mitigation Report shall include:

- Role and principal duties of the conflicted Investigator in the research project;
- How the conditions of this Management Plan and Policy were or were not followed;
- How the proposed actions are 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.

Application Certification:

The company shall Certify in each application for funding that the Institution:

1. Has in effect an up-to-date written, and enforced administrative process to identify and manage FCOIs related to all PHS research projects.
2. Shall promote and enforce Investigator compliance with the regulation pertaining to disclosure of SFIs.
3. Shall manage FCOIs and provide initial and ongoing FCOI reports to PHS/NIH.
4. Agrees to make information available upon request relating to any Investigator disclosure of financial interest and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI.
5. Fully comply with the requirements of the regulation.

Designated Institutional Official(s); i.e.: Responsible Individual

The company shall:

1. Designate an Institutional Official(s), the Responsible Individual, to solicit & review disclosure statements from each Investigator planning to participate in, or is participating in, PHS/NIH-funded research. This Responsible Individual for the Company is the Director of Quality and Regulatory Affairs. The Responsible Individual will be made aware of any possible financial conflicts of interest by the President and/or Controller at the Company, who will both be trained on the policy.
2. Provide guidelines to identify conflicting interests related to proposed or PHS/NIH-funded research. This policy provides those guidelines.
3. Designated Institutional Official(s) develop management plans that specify the actions that have been, and shall be, taken to manage FCOI. This Policy provides that Management Plan. The person who shall update this Management Plan is the Responsible Individual.

Maintenance of Records

The Company shall maintain records of all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of FCOI) and all actions under the Institution's policy or retrospective review, if applicable

1. for at least three years from the date of submission of the final expenditures report or, where applicable,
2. from other dates specified in 45 C.F.R. 74.53(b) and 92.42 (b) for different situations.

Reporting:

The Responsible Individual and Controller shall assure that any FCOI is reported on the Web Site prior to the expenditure of any funds under the award and

Within 60 days for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award

Current requirements, plus annual updates on any previously-identified FCOI for the duration of the research project (including during an extension with or without funds)

The Company shall, within 120 days of the Company's determination of non-compliance, complete a retrospective review of the investigator's activities and the NIH-funded research project to determine if there was bias in the design, conduct, or reporting of such research. Institution is required to document the retrospective review.

The Responsible Individual shall work with the Controller to submit the following reports to the NIH:

- A Mitigation Report required if bias is found.
- Provide initial and ongoing FCOI reports:
 - Prior to the expenditure of funds
 - During the period of award
 - Within 60 days of identifying a new FCOI
 - Annually
 - Report on the status of FCOI and any changes in management plan
 - Due at same time as when grantee submits annual progress report, including multi-year progress report, or at time of extension
- All FCOI reports are submitted to NIH through the eRA Commons FCOI Module. It shall contain:
 - Grant number;
 - PD/PI or contact PD/PI;
 - Name of Investigator with the FCOI;
 - Name of the entity with which the Investigator has an FCOI;
 - Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
 - Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amts between \$20K-100K by increments of \$20K; amts above \$100K by increments of \$50K or a statement that a value cannot be readily determined;
 - A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
 - Key elements of the Institution's management plan.

Public Accessibility of FCOIs on the website

- Prior to expenditure of funds, make certain information concerning FCOIs held by senior/key personnel publicly accessible via a Web site or provide written response within five business days of a request.
 - Update the website annually and within 60 days of identifying any new FCOIs when posting FCOIs to website
 - Retain information for three years
- Information to be made publicly available includes the following:
 - Investigator's name;
 - Investigator's title and role with respect to the research project;
 - Name of the entity in which the SFI is held;
 - Nature of the SFI; and
 - Approximate dollar value of the SFI (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 references to public prices or other reasonable measures of fair market value.

Retrospective Review:

- Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI, failure by the Institution to review or manage an FCOI, or failure to comply with the management plan, the institution shall within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research.
- Notify NIH promptly and submit a Mitigation Report when bias is found.
- Documentation of the key elements of a 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 an 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 and conclusions of the review.

If results of the retrospective review warrant, update previously submitted FCOI report

- If bias is found through retrospective review, notify the NIH Awarding Component promptly (through the eRA Commons) and submit a Mitigation Report.
 - Mitigation Report
 - Key elements documented in retrospective review
 - Description of the impact of the bias on the research project
 - Plan of action(s) to eliminate or mitigate the effect of the bias
 - Thereafter, submit FCOI reports annually.

Electronic Research Administration (eRA) Commons FCOI Module

The reporting tool for submitting FCOI reports for grants and cooperative agreements is the eRA Commons FCOI Module. This reporting tool is being enhanced and currently allows the Company to:

- Initiate and send FCOI Reports to NIH electronically through the eRA Commons FCOI Module
- Revise or update a previously submitted FCOI report (future enhancement)
- Submit a Mitigation Report when bias is found (future enhancement)
- Search previously created records
- Edit a previously submitted record
- Respond to a request for additional information
- Rescind a previously submitted record
- View history of actions

To prepare, Institutional Signing Officials must assign FCOI roles to users in eRA Commons.

- More information on the FCOI Module can be found at http://era.nih.gov/services_for_applicants/other/fcoi.cfm

HHS Authority

The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in NIH-funded research. The HHS authority applies before, during, or after an award with regard to any Investigator disclosure of financial interests, regardless of whether or not the disclosure resulted in the Institution's determination of an FCOI.

- Contact with the NIH Mailbox for inquiries
 - FCOICompliance@mail.nih.gov
 - OER FCOI Web Site
 - <http://grants.nih.gov/grants/policy/coi/>
 - FAQs posted on 9/30/2011. See NIH Guide Notice NOT-11-121 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-121.html>

Enforcement:

The President, with the advice and consult of the Responsible Individual, shall have the authority to enforce this Policy. Sanctions, administrative actions, and other actions up to and including termination may be taken to enforce this policy and ensure Investigator compliance.

The President may require that one or more of the following actions be taken in order to manage, reduce, or eliminate a potential Conflict of Interest:

- a. Disclosure of Significant Financial Interests, including to the public, human subjects, researchers and other participants and publishers;
- b. Monitoring of PHS-funded Research by independent researchers and/or reviewers, disinterested individuals or committees;
- c. Disqualification from participation in all or a portion of the PHS-funded Research;
- d. Requiring that Significant Financial Interests be divested, restructured, or placed in blind trust;
- e. Modification or severance of relationships that create a potential Conflict of Interest;
- f. Changing terms of agreement relating to the PHS-funded Research;

- g. Requiring that Investigator participation in the recruitment or consent of subjects in human subjects PHS-funded Research be prohibited or restricted;
- h. Requiring additional disclosures or actions with respect to matters before the Research Management Team; or
- i. Requiring non-participation in any business transactions between the Company and parties to agreements involving sponsored PHS-funded Research.

Revision of Policies:

This policy shall be reviewed upon changes to the Federal Regulation and revised as appropriate.