Conflict of Interest for DHHS Funded Programs  
(Revised 08/06/2013)

Overview

Additional training, disclosure and reporting requirements exist for all Investigators working on research funded by the Department of Health and Human Services (DHHS). This policy promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of any research by Kitware will be biased by any conflicting financial interest of a Kitware employee including an employee’s spouse and dependent children. This policy is in compliance 42 CFR Part 50, subpart F and 45 CFR Part 94.

Definitions

Investigator means the principal investigator assigned to a contract (also referred to as a project) and any other person who is responsible for the design, conduct, or reporting of research. Any requirements or restrictions applicable to the Investigator extends to the Investigator’s spouse and dependent children. Within the Company, the Investigator is the employee directing the project.

Significant financial interest 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 responsibilities at Kitware:

(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 responsibilities at Kitware; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by Kitware, 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 details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Kitware will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest.

(3) Further, employees performing the role as the Investigator on a grant or contract must also disclose recruitment bonuses paid for human subject research participants or for reaching a performance goal within a specific time frame, as well as being offered a finder's fee for referral of potential research subjects.

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

- Salary, royalties or other remuneration from Kitware, including intellectual property rights assigned to Kitware and agreements to share in royalties related to such rights.
- Any ownership interests in Kitware.
- 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.

**Training**

All employees working on DHHS funded programs will be informed of Kitware’s policy on conflicts of interest for DHHS funded programs, the employee's responsibilities regarding disclosure of significant financial conflicts interests, and of applicable regulations. All employees working on DHHS funded programs will be required to complete conflict of interest training when hired and at least every four years, and immediately when any of the following circumstances apply:

1. Kitware revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

2. Kitware finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.
**Reporting**

**Employees**

All employees working on DHHS funded programs must review this Policy and sign the related Conflict of Interest Disclosure Form at the point of hire, annually thereafter, and from time to time as determined by Company Management. The completed form should be sent to the Human Resource Department.

In addition, employees will be required to complete a new disclosure form when appointed to work on assignments that either (i) create new potential conflict for the employee or the institution, vendor, collaborator, partnering firm, or subcontractor with whom the Company conducts business, or (ii) change the facts applicable to previously disclosed potential conflicts. Such a report must be filed within 30 days of identification of the conflict.

**Corporate Leadership, Company Management, Investigators, Compliance Officer**

In addition to the above employee reporting requirements, Corporate Leadership, Company Management, Investigators and the Compliance Officer are responsible to oversee, report and mitigate conflict when identified by themselves or other employees.

**Managing Conflicts of Interest**

After a conflict has been identified and reported to the Human Resources Department, the Compliance Officer will review and work with the employee and Company Management to mitigate as necessary or contractually required. This review must be completed prior to expenditure of any funds for a project related to the conflict of interest. If the conflict of interest is identified (whether by a disclosure from the Investigator or some other means) in the course of an ongoing project, the Compliance Officer review the conflict and implement a management plan, if necessary, within 60 days. Depending upon the nature of the conflict, Kitware may determine that additional interim measures are necessary with regard to the Investigator’s participation in the project between the date of the disclosure and the completion of the Compliance Officer’s review.

Management of an identified conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report. Whenever a management plan is implemented, Kitware will monitor Investigator compliance with the plan on an ongoing basis until the completion of the related project.

Initial and ongoing conflict of interest reports will be provided to government agencies, funding sources and/or members of the public whenever required by regulations or contractual obligations.

In the event that a conflict of interest is discovered or reported, restrictions and/or actions may be imposed to ensure management, reduction or elimination of such conflict. These restrictions and/or actions might include:

a. public disclosure of financial conflicts of interest (reporting to the funding source or government agency and when presenting or publishing the research),

b. for research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants,
c. monitoring of research by independent reviewers,
d. modification of research or work plans,
e. change of personnel or personnel responsibilities, or disqualification from participation in all or portions of assignments,
f. reduction or elimination of the financial interest (e.g. sale of an equity interest), or
g. severance of relationships that create conflicts of interest.

Determining whether a conflict of interest exists can sometimes be difficult. Employees are strongly encouraged to seek advisement from the Compliance Officer before entering into any transaction or relationship that may potentially give rise to a conflict of interest.