

# Financial Conflict of Interest in PHS-Funded Projects

## I. POLICY

Aptitude Medical Systems Inc. (Aptitude) strives to create a research climate that promotes objectivity in research by establishing standards such that the design, conduct and reporting of Public Health Service (PHS, which includes NIH) funded research is free from bias resulting from financial conflict of interest (FCOI).

This policy is applicable to each employee who is planning to or is participating in research activity that is either partially or wholly supported by PHS funds. Each such employee must:

1. **disclose** his or her significant financial interests (SFI) in non-Aptitude entities that would appear to be related to the employee's professional responsibilities on behalf of Aptitude;
2. **comply** with a FCOI management plan, if a FCOI is identified; and
3. **undergo** FCOI training, at least once every four years.

Disclosure of SFI is essential for Aptitude to determine if a FCOI exists, and in cases of FCOI determine how it will be managed and reported in full compliance with government regulation. Non-disclosure of SFI or non-compliance with FCOI management plan may subject the employee to employment discipline including, without limitation, suspension or termination of employment.

## II. DEFINITIONS

A. *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.

B. Significant Financial Interest (SFI) exists if the value of remuneration received by the employee, employee's spouse or dependent children that reasonably appear to be related to the employee's Aptitude responsibilities exceeds \$5000;

1. Including:
  - Salary or other payments for services (e.g., consulting fees or honoraria) received in the twelve months preceding disclosure;
  - Equity interests (e.g., stocks, stock options or other ownership interests), however, equity interest in a non-publicly traded entity, no matter the amount, constitutes an SFI; and,
  - Income from intellectual property rights owned by the employee.
2. Excluding
  - Salary, royalties, stock, stock options or other remuneration from Aptitude;
  - Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, derived from excluded sources;
  - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the employee does not directly control the investment decisions; and,

- Unlicensed intellectual property owned by the employee that does not generate income.  
Note that Intellectual property owned by Aptitude is excluded.

3. SFI disclosure also includes travel. Specifically, externally funded reimbursed or sponsored travel that would appear to be related to employee's Aptitude responsibilities, however, that is not funded by Aptitude. Such travel must be disclosed, no matter the amount, except when the expenses are covered by any of the excluded sources.

Note that the threshold of \$5000 is applied to the aggregation of 1a and 1b, or to 1c.

*C. Employee's professional responsibilities on behalf of Aptitude* means conducting research, submitting patent applications, publication, technical committee membership and, teaching as adjunct faculty at an Institute of higher education.

*D. An excluded source means* a source of remuneration that is excluded from disclosure. With reference to the SFI (2b and 3), excluded sources are – federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

### **III PROCEDURE**

Employees who are planning to or participating in research activity that is either partially or wholly supported by PHS funds must disclose their SFI in a timely fashion, to the designated Aptitude FCOI official. The designated Aptitude FCOI official will determine whether the SFI constitutes an FCOI. Consistent with the attached, Protocol for Handling Financial Conflict of Interest, if the SFI is determined to be an FCOI, the Aptitude Management Team (Aptitude MT) will take actions to discuss and approve the implementation of an FCOI management plan consistent with government regulation and, furthermore, to promptly notify the PHS funding component (e.g., NIH) via a FCOI report.

As a part of the FCOI management plan, the Aptitude MT will decide one or more actions depending upon the situation, including requiring certain disclosure in public presentations, employee role reassignment, reduction or elimination of the financial interest sanctions (e.g., sale of an equity interest) or severance of relationships that create financial conflicts. Employees with an identified FCOI must comply with the FCOI management plan.

### **IV RELATED POLICIES AND PROCEDURES**

Protocol for Handling Financial Conflict of Interest (See below).

### **V ADMINISTRATION**

The designated Aptitude FCOI official is responsible for administration of this policy.

## **Protocol for Handling Financial Conflict of Interest**

This protocol along with the policy and procedure titled, Financial Conflict of Interest in PHS-Funded Projects, constitute the Aptitude FCOI policy. Capital terms in this protocol shall have the same meaning as set forth in the policy. This protocol outlines the procedure that will be followed as per regulation (Title 42 CFR 50.601-50.607).

This document specifies the FCOI protocol for PHS-funded research: that is the step-by-step implementation of the Aptitude FCOI policy.

### **1. Who is required to disclose financial interests**

Employees planning to or participating in research activity that is either partially or wholly supported by PHS funds are required to disclose financial interests (“PHS-funded Investigators”).

### **2. SFI disclosure**

PHS-funded Investigators are required to disclose SFIs to the Aptitude FCOI official, as follows:

1. Employees planning to participate in PHS-funded research are required to disclose all SFI's prior to submission of an application for PHS-funded research.
2. Once the research project has been funded all PHS-funded investigators shall submit SFI Disclosures within thirty (30) days of acquiring any new or increased SFI,
  - o When a new investigator joins an ongoing PHS-funded project, the investigator shall submit SFI disclosures within thirty (30) days of joining the project.
3. All PHS-funded investigators shall submit an updated SFI disclosure annually.
4. SFI disclosures (except travel) must include the following information:
  - o Identity of the sponsor/organizer; and
  - o Nature of SFI (e.g., salary, license income, stock).
5. Externally funded travel also constitutes SFI, and therefore the disclosure requirements in 2 (i)-(iii) apply. That is, PHS-funded investigators shall submit SFI Disclosures for externally funded travel: prior to submission of an application for PHS-funded research; and for PHS-funded projects within thirty (30) days of externally funded travel and in an annual update. The following travel related information must be disclosed:
  - o Purpose,
  - o Identity of the sponsor/organizer,
  - o Destination, and,
  - o Duration.

### **3. Review of disclosures**

All SFI disclosures, including those submitted by a new investigator who joins an ongoing PHS-funded project, will be reviewed by the designated Aptitude FCOI official. The review will determine whether an SFI is related to the PHS-funded research and therefore an FCOI. The designated Aptitude FCOI official may involve the relevant investigator in the review, and request additional information from the investigator.

When an SFI that was not disclosed by a PHS-funded Investigator in a timely manner is identified, the designated Aptitude FCOI official will determine if FCOI exists, develop and implement a management plan within sixty (60) days after the identification of the SFI. In addition, the designated Aptitude FCOI official will conduct a retrospective review of SFIs for the PHS-funded investigator within one hundred twenty (120) days and document it.

#### **4. Management of FCOI**

For each disclosure that leads to determination of FCOI, the Aptitude MT will discuss and approve the implementation of a management plan developed by the designated Aptitude FCOI official. PHS-funded Investigators with an identified FCOI must comply with the management plan. The management plan will include the following elements at a minimum:

1. The role and principal duties of the conflicted PHS-funded Investigator in the research project;
2. conditions of the management plan (see examples below);
3. How the management plan is designed to safeguard objectivity in the research project;
4. Confirmation of the PHS-funded Investigator's agreement to the management plan; and
5. How the management plan will be monitored to ensure PHS-funded Investigator compliance.

Examples of conditions or restrictions that might be imposed to manage a PHS-funded Investigator's FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board(s));
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

#### **5. Reporting FCOI to PHS Awarding Component (e.g. the NIH)**

Based on the FCOI management plan, the designated Aptitude FCOI official will submit an initial FCOI report to the PHS-funding component, for example NIH. The report will be submitted, for example using eRA Commons for NIH, and consist of all elements required by the regulation.

The FCOI report for will be submitted prior to the expenditure of funds under the Notice of Award. FCOIs identified during the period of award will be submitted to NIH within sixty (60) days of identification, including for new investigators joining an ongoing PHS-funded project.

Annual FCOI reports (or revised reports as a result of retrospective reviews) will also be submitted and will include the status of financial conflict, i.e., whether the financial conflict is still being managed or explains why the financial conflict no longer exists. These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

## **6. Training for FCOI**

PHS-funded Investigators must undergo training with respect to this Policy and PHS FCOI rules and regulations, as follows:

1. When a new employee joins Aptitude;
2. Prior to participating in PHS-funded research, and at least once every four years;
3. When the Aptitude FCOI policy changes in a manner that effects PHS-funded Investigator disclosure or compliance requirements; and,
4. If Aptitude MT determines that a PHS-funded Investigator is not compliant with the FCOI Policy or an FCOI Management Plan.

NIH web-based training (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) will be used. Employees must save and print the FCOI Certificate as proof of completion.

## **7. Noncompliance and remedies**

If an investigator has failed to comply with a management plan or, for whatever reason, an FCOI is one that was not identified, reviewed or managed in a timely manner, the designated Aptitude FCOI official shall, within 120 days of the determination of noncompliance, conduct a retrospective review of the investigator's activities and the research project to determine whether any PHS-funded research or portion thereof conducted during the period of noncompliance was biased in design, conduct or reporting. The review shall be documented consistent with the FCOI Regulations [§60.605(a)(3)(ii)(B)]. If bias is found during the course of the review, the designated Aptitude FCOI official will promptly notify the PHS Awarding Component (which may take its own action and/or require further action by Aptitude and/or the investigator, as it deems appropriate) and submit a mitigation report consistent with the FCOI Regulations [§60.605(a)(3)(iii)]. If appropriate, the designated Aptitude FCOI official will update the previously submitted FCOI report. In any event, the designated Aptitude FCOI official shall submit FCOI reports annually thereafter.

For clinical research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment was designed, conducted, or reported by an investigator with an FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the investigator shall disclose the FCOI in each public presentation of the results of the research (such as articles, manuscripts and oral presentations) and Aptitude shall request an addendum to previously published presentations.

## **8. Retention of records**

Records of financial disclosures and any resulting action will be maintained for three (3) years from the date of submission of the final expenditures report.

## **9. Subrecipient compliance**

When working with a subrecipient, a written agreement will be put in place to clarify: (a) which organization's (prime awardee or subrecipient) FCOI policy will be followed, and, (b) in either case, clarify the timeline for disclosure and reporting. Note that the prime awardee is responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest.

## **10. Public Accessibility**

As required by PHS regulation, the Aptitude FCOI policy is made accessible on Aptitude web site.

If a PHS-funded investigator holds financial interests that are determined to be FCOI, as required by PHS regulation, these will also be posted on the web site, as follows:

1. Include the minimum elements required by the regulation;
2. Update within sixty (60) days of a newly identified FCOI;
3. Update annually; and
4. Remain available for three (3) years.