

# *Financial Conflict of Interest (FCOI) Policy* *Atomo, Inc.,*



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## Introduction

This document constitutes the Financial Conflict of Interest (FCOI) policy of Atomo, Inc. (Atomo) that is established in accordance with 2011 FINANCIAL CONFLICT OF INTEREST (FCOI) REGULATION, PROMOTING OBJECTIVITY IN RESEARCH 42 CFR Part 50, Subpart F.

### References

The FCOI Regulation (referred to in this policy as “The Regulation”)  
(<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F> )

The NIH Frequently Asked Questions (FAQs) page related to The Regulation:  
(<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52878>)

## Definitions

The following terms are defined in The Regulation.

*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.” (42 CFR 50.603 “Financial conflict of interest”)

“*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 PHS, or proposed for such funding, which may include, for example, collaborators or consultants.” (42 CFR 50.603 “Investigator”)

## Atomo Responsibilities

### *Policy maintenance and public disclosure*

Atomo will maintain an up to date, written, enforced policy on FCOI that complies with The Regulation and will make the policy publicly accessible at the company web site using the URL: <https://www.atomohealth.com/privacy-policy/>

Prior to Atomo’s expenditure of any funds under a PHS-funded research project, Atomo will publicly disclose at the same URL cited above any significant financial interest (SFI) that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel of the research project.
2. Atomo determines that the SFI is related to the PHS-funded research.
3. Atomo determines that the SFI is a FCOI.

If such a public disclosure is made, the following information will be provided on its web site:

1. Project number
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used.
3. Name of the Investigator with the FCOI
4. Name of the entity with which the Investigator has a FCOI.
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
6. Approximate value of the financial interest ( \$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

### *Certification during applications*

Atomo will Certify, in each application for funding for Public Health Service (PHS)-funded research, that Atomo:

1. Has in effect an up to date, written, and enforced administrative process to identify and manage FCOIs with respect to all research projects for which funding is sought or received from the PHS
2. Shall promote and enforce Investigator compliance with The Regulations requirements including those pertaining to disclosure of SFIs.
3. Shall manage FCOIs and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with The Regulation
4. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and Atomo's review of, and response to, such disclosure, whether or not the disclosure resulted in Atomo's determination of a FCOI.
5. Shall fully comply with the requirements of The Regulation

### *Training*

Atomo will inform each investigator of Atomo's FCOI policy and the Investigator's responsibilities regarding disclosure of SFIs, and of The Regulation.

Atomo will require each investigator to complete the FCOI training module (<https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>) at these times:

1. Prior to engaging in research related to any PHS funded grant, and
2. At least every four years, and
3. Immediately when any of the following circumstances apply:
  - a. Atomo revises its FCOI policies or procedures in any manner that affects the requirements of Investigators; or
  - b. An Investigator is new to Atomo; or
  - c. Atomo finds that an Investigator is not in compliance with Atomo's FCOI policy or management plan.

Training records will be maintained by the Atomo Chief Operating Officer (COO) and Investigators should keep a copy.

### *Working with subrecipients such as contractors*

If the PHS-funded research involves subrecipients, then Atomo will adhere to 42 CFR 50.604(c) and will ensure that the provisions of that section are incorporated in writing. This will include, incorporating as part of a written agreement with the subrecipient, terms that establish whether the financial conflicts of interest policy of Atomo or that of the subrecipient will apply to the subrecipient's Investigators.

If an FCOI is identified by the sub-award recipient, they are required to notify the PI and CEO of Atomo of the existence of the FCOI within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced, or eliminated in accordance with federal regulations.

Such agreements will require that FCOI reports be provided to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this

subpart, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

### *Designated Institutional Officials*

Atomo designates The Chief Executive Officer (CEO) and The Chief Operating Officer (COO) of Atomo as the institutional officials to solicit and review disclosures of SFIs from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

### *Designation of investigators*

The Principal Investigator (PI) of the research will designate all the Investigators of the research and communicate this to the COO who will be responsible for ensuring that all required SFI disclosures are completed and reviewed by the Designated Institutional Officials.

### *Disclosure of Significant Financial Interests (SFIs)*

Atomo will require that each Investigator who is participating or planning to participate in the PHS-funded research disclose to Atomo's designated official(s) the Investigator's SFIs (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research. The disclosure will include all details that are mentioned in the Definitions section.

Each Investigator identified by the PI will be required to complete SFI Disclosure Form:

1. Before participating in any PHS/NIH funded research activities,
2. Annually during the period of award, and
3. Within 30 days of discovering or acquiring a new SFI. The discovery or acquirement may be due to marriage, purchase, or inheritance.

Atomo designates the first week of August of each year as the time for the annual disclosure of SFIs.

### *Guidelines for SFIs*

In addition to The Regulation, this definition also considers the NIH guidelines provide here:

<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52866>

Specifically FAQ E9, E20 and E24

A Significant Financial Interest (SFI) 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, that exceeds \$5000.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel that exceeds \$5000 (*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 located in the United States, an United States 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 a United States 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 Atomo'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 Atomo to the Investigator if the Investigator is currently employed or otherwise appointed by Atomo, including intellectual property rights assigned to Atomo and agreements to share in royalties related to such rights; any ownership interest in Atomo held by the Investigator, if Atomo 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 located in the United States, a United States 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 a United States Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, a United States 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 a United States Institution of higher education. “

Atomo will provide guidelines for the Designated Institutional Officials to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is a FCOI. See section below “Determination of whether an SFI is related to PHS-funded research” and “Determination of whether an SFI is a FCOI”.

#### *Determination of whether an SFI is related to PHS-funded research*

Atomo's Designated Officials will evaluate whether an Investigator's SFI is related to PHS-funded research by determining whether the SFI:

1. Could be affected by the PHS-funded research; or
2. Is in an entity whose financial interest could be affected by the research.

### *Determination of whether an SFI is a FCOI*

Atomo's Designated Officials will evaluate whether an Investigator's SFI is a FCOI by using this guideline:

A FCOI exists when the Designated Officials of Atomo reasonably determine that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

### *Managing FCOIs*

When Atomo identifies a FCOI, including those of a subrecipient, Atomo will take necessary actions to manage the FCOI. Specifically, the following actions will be taken.

1. Atomo will develop and implement a management plan appropriate for the FCOI prior to expenditure of any PHS funds for the project. This plan will specify the actions that have been taken and will be taken to manage the FCOI. This plan will also include the following items:
  - 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
  - f. Other information as needed.

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

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

2. Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses an SFI or an existing Investigator discloses a new SFI to Atomo, the designated official(s) of Atomo will, within sixty days: review the disclosure of the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI exists; and, if so, implement a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.
3. Whenever Atomo identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by Atomo, the designated official(s) will, within sixty days: review the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI exists; and, if so:
4. Implement a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward;
5. and...
  - a. In addition, whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by Atomo to constitute a FCOI; failure by Atomo to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, Atomo shall, within 120 days of Atomo's 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.
  - b. The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all the following key elements:
    - i. Project number
    - ii. Project title
    - iii. PD/PI or contact PD/PI if a multiple PD/PI model is used.
    - iv. Name of the Investigator with the FCOI
    - v. Name of the entity with which the Investigator has a FCOI.
    - vi. Reason(s) for the retrospective review
    - vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
    - viii. Findings of the review
    - ix. Conclusions of the review
6. Based on the results of the retrospective review, if appropriate, Atomo will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Atomo will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and Atomo's plan of

action or actions taken to eliminate or mitigate the effect of the bias. Thereafter, Atomo will submit FCOI reports annually, as specified in The Regulation.

7. See also the section below titled “Note on Remedies”, paragraph (a)

### *Reporting*

The Atomo COO is responsible for reporting matters related to SFIs and FCOIs.

Any FCOI report shall 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 Atomo’s management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

1. Project number
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used.
3. Name of the Investigator with the FCOI
4. Name of the entity with which the Investigator has a FCOI.
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
6. 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.
7. A description of how the financial interest relates to the PHS-funded research and the basis for Atomo’s determination that the financial interest conflicts with such research.
8. A description of the key elements of Atomo’s management plan, including:
  - a. 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
  - f. Other information as needed.

This reporting includes:

1. Initial report: Atomo will provide the sponsor a report of any FCOI before the expenditure of any funds, in accordance with The Regulation.
2. As needed reporting: Atomo will report any FCOI that arises during the research project. This will be done within 60 days after Atomo determines that a new FCOI exists.
3. Annual FCOI reporting: Atomo will provide an annual report for any FCOI previously reported to the sponsor. This report will address the status of the FCOI and any changes in the Atomo management plan for this FCOI. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. Atomo shall 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.

### *Monitoring*

If Atomo implements a management plan for any FCOI, Atomo will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

### *Violations of FCOI Policy*

Atomo requires that all investigators comply with all aspects of this policy. Any investigator who violates any aspect of the policy, including failure to disclose a SFI or failure to follow a FCOI management plan, may face disciplinary actions determined by Atomo management.

If an investigator fails to comply with The Regulation, Atomo will notify the research sponsoring agency as required by The Regulation. See section “Note on Remedies” for additional details.

### *Record keeping*

Atomo will maintain records relating to all Investigator disclosures of financial interests and Atomo’s review of, and response to, such disclosures (whether or not a disclosure resulted in Atomo’s determination of a FCOI) and all actions under Atomo’s policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS. Upon request, Atomo will supply information regarding these records.

### *Additional considerations for research involving Human Subjects*

For research that involves Human Subjects, the IRB responsible for the research protocols will be notified of any FCOI. Research will not begin until the IRB has confirmed that all appropriate steps have been taken and that research can proceed.

### *Note on Remedies*

From 42 CFR 50.606, it is noted that:

- a. If the failure of an Investigator to comply with Atomo’s financial conflicts of interest policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, Atomo shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Atomo for further action, which may include directions to Atomo on how to maintain appropriate objectivity in the PHS-funded research project.
- b. The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Atomo disclosure of financial interests and Atomo’s review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in Atomo’s determination of a FCOI. Atomo is required to submit, or permit on site review of, all records pertinent to compliance with this subpart. To the extent

permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that Atomo has not managed the FCOI in accordance with this subpart. The PHS Awarding Component may determine that imposition of specific award conditions under 45 CFR 75.207, or suspension of funding or other enforcement action under 45 CFR 75.371, is necessary until the matter is resolved.

- c. In any case in which the HHS 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 has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by Atomo as required by this subpart, Atomo shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations .