

Ricoh USA, Inc.**Financial Conflict of Interest Policy Applicable to****Ricoh 3D for Healthcare Research Funded Under Public Health Service Grants or Cooperative Agreements****1. Purpose**

- a. The purpose of this Policy is to promote objectivity in Research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of Research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest, as contemplated by the FCOI Regulations.
- b. The FCOI Regulations require that Investigators disclose to Ricoh any Significant Financial Interests related to their Institutional Responsibilities at Ricoh.
- c. As of the last revision date of this Policy, the FCOI Regulations are available at: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>.

2. Definitions

- a. Capitalized terms used in this Policy—but not defined in this Policy—have the meaning given to them in the FCOI Regulations. As of the last revision date of this Policy, those definitions are available at: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>.
- b. In this Policy, the following terms have the meanings given to them below:
 1. **"Designated Officer"** means the Ricoh Ethics Officer.
 2. **"FCOI Regulations"** means 42 CFR part 50, Subpart F, as amended.
 3. **"Investigator Managers"** means managers of Investigators planning to participate in, or participating in, Research funded under PHS grants or cooperative agreements on Ricoh's behalf.
 4. **"Policy"** means this Ricoh USA, Inc. Financial Conflict of Interest Policy Applicable to Ricoh 3D for Healthcare Research Funded under Public Health Service Grants or Cooperative Agreements.
 5. **"Ricoh"** means Ricoh USA, Inc.
 6. **"Ricoh 3D for Healthcare"** means the internal business team at Ricoh primarily engaged in activities to advance the application of additive manufacturing technologies in medical device and other healthcare spaces. As of the last revision date of this Policy, Ricoh 3D for Healthcare is managed by the Managing Director, Additive Manufacturing, who reports to the Ricoh Chief Digital Services & Delivery Officer.

3. Applicability

This Policy applies to individuals supporting the Ricoh 3D for Healthcare business within Ricoh who are:

- a. Investigators planning to participate in, or participating in, Research funded under PHS grants or cooperative agreements on Ricoh's behalf; and
- b. Investigator Managers.

4. Compliance

- a. In connection with Research funded under PHS grants or cooperative agreements, each Investigator and Investigator Manager must comply with this Policy and all applicable requirements under the FCOI Regulations.
- b. Investigator Managers are responsible for ensuring that Investigators comply with this Policy and all applicable requirements under the FCOI Regulations.
- c. Without limiting the previous sections:
 1. Disclosure
 - a. Before submitting an application for funding, the Principal Investigator and all other Investigators must have disclosed to the Designated Officer an up-to-date listing of their Significant Financial Interests

(including those of their spouse and dependent children). Any new Investigator, who, after the submission of an application for funding, or during the Research project, plans to participate in the project, must similarly disclose their Significant Financial Interests to the Designated Officer. Investigator Managers must coordinate this submission to the Designated Officer.

- b. During the period of the award, each Investigator who is participating in Research must submit an updated disclosure of Significant Financial Interests at least annually. The disclosure must include any information that was not disclosed initially to Ricoh or in a subsequent disclosure of Significant Financial Interest under this Policy and must include updated information regarding any previously disclosed Significant Financial Interests.
 - c. In addition, each Investigator must submit an updated disclosure of Significant Financial Interests (including reimbursed travel) within 30 days of discovering or acquiring (for example, through purchase, marriage, or inheritance) a new Significant Financial Interest.
2. Training Requirements
- a. Each Investigator must review this Policy and complete training on this Policy (1) before engaging in Research related to any award, (2) at least every four years during the period of the award, and (3) immediately when any of the following circumstances apply:
 - i. Ricoh revises this Policy, or procedures related to this Policy, in a manner that affects the requirements of Investigators (training is to be completed within the period specified in communications announcing the changes);
 - ii. An Investigator is new to Research under an award (training must be completed before participating in the Research); or
 - iii. Ricoh finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training must be completed within 30 days in the manner specified by the Designated Officer).
 - b. In fulfillment of the training requirement, Investigators must complete the National Institutes of Health's Financial Conflict of Interest tutorial located at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. All Investigators must print a certification of completion at the end of training, provide a copy to their Investigator Manager, and retain it for audit purposes. Investigator Managers must also retain a copy of the training for audit purposes.

5. Failure to Comply with this Policy

- a. Any failure by an Investigator or an Investigator Manager to adhere to this Policy may be cause for disciplinary action, up to and including termination of employment.
- b. It is a violation of this Policy to apply for, or expend funds from, an award unless all applicable Investigators have complied with this Policy and have agreed, in writing, to comply with any applicable Designated Officer-approved FCOI management plan.
- c. When an FCOI is not identified or managed in a timely manner, the Investigator and their Investigator Managers will timely cooperate in Ricoh's review and attempts to remedy the matter in the time and manner that Ricoh specifies, which may include (among other activities):
 1. Completing a retrospective review of the Investigator's activities and the Research project to determine any bias in the design, conduct, or reporting of the Research;
 2. Documenting the retrospective review consistent with the FCOI Regulations;
 3. Documenting Ricoh's determination as to whether any Research (or portion of the Research) conducted during the period of the Investigator's non-compliance with this Policy or an FCOI management plan was biased in the design, conduct, or reporting of the Research;
 4. Notifying the awarding body in writing; and
 5. Submitting a mitigation report to the awarding body that will address the following:
 - a. Impact of the bias on the Research project; and
 - b. Ricoh's plan of action or actions taken to eliminate or mitigate the effect of the bias.

6. Review by the Designated Officer

- a. The Designated Officer will review:
 1. Disclosures required under this Policy or the FCOI Regulations; and
 2. Significant Financial Interests that have been identified in the disclosures.

- b. The interests identified in the disclosures will be compared to the relevant award to determine if there is a Significant Financial Interest related to the award and, if so, whether the Significant Financial Interest creates a Financial Conflict of Interest related to the award.

7. Guidelines for Determining “Relatedness” and Financial Conflict of Interest

- a. The Designated Officer will determine whether an Investigator’s Significant Financial Interest is related to the relevant award and, if so, whether the Significant Financial Interest is a Financial Conflict of Interest.
- b. An Investigator’s Significant Financial Interest is related to the Research under an award when the Designated Officer reasonably determines that the Significant Financial Interest:
 - 1. Could be affected by the Research conducted under the award, or
 - 2. Is in an entity whose Financial Interest could be affected by the Research.
- c. The Designated Officer may involve the Investigator, Investigator Managers, and others in the determination of whether a Significant Financial Interest is related to the Research supported by the award.
- d. A Financial Conflict of Interest exists when the Designated Officer reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the relevant Research.
- e. In determining if an Investigator’s Significant Financial Interest is related to the Research under an award, and if so, whether the relationship creates a Financial Conflict of Interest, the Designated Officer will consider the role of the Investigator and the opportunity (if any) to bias the results, the nature of the Research being proposed, and the value of the Significant Financial Interest in relation to the size and value of the entity. The Designated Officer may also consider other factors, including (without limitation):
 - 1. Whether the goal of the Research is to evaluate an invention linked to the Significant Financial Interest (such as where the Significant Financial Interest is a patent or an interest in a company that has licensed the invention);
 - 2. The magnitude of the Significant Financial Interest;
 - 3. The number and nature of relationships an Investigator has with an entity;
 - 4. Whether the goal of the Research is to validate or invalidate a particular approach or methodology that could affect the value of the Significant Financial Interest;
 - 5. Whether sufficient external review of the Research and the reporting of Research results exist to mitigate undue bias; and
 - 6. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a Significant Financial Interest.

8. Management of Significant Financial Interests that Pose Financial Conflicts of Interest

- a. If a Financial Conflict of Interest exists, then the Designated Officer will determine how the conflict should be avoided or managed to mitigate undue bias.
- b. In making those determinations, the Designated Officer will be guided by the principles discussed in this Policy and the FCOI Regulations and will also take into consideration whether the Investigator’s ongoing role is necessary to continue advancing the Research.
- c. Examples of conditions that might be imposed to Manage a Financial Conflict of Interest include (but are not limited to):
 - 1. Public disclosure of financial conflicts of interest (for example, when presenting or publishing the Research);
 - 2. Modification of the Research plan;
 - 3. Change of personnel or personnel responsibilities;
 - 4. Disqualification of personnel from participation in all or a portion of the Research; and
 - 5. Severance of relationships that create financial conflicts.
- d. If the Designated Officer determines that a Financial Conflict of Interest exists, then the Designated Officer will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the relevant Investigator and Investigator Managers.
- e. No expenditures on an award are allowed until the Investigator and the relevant Investigator Managers have complied with the requirements of this Policy and have agreed (in writing) to comply with any plans that the Designated Officer determines are necessary to Manage the FCOI.
- f. The Designated Officer will direct an appropriate individual to communicate to the applicable awarding body to notify the awarding body of the existence and the nature of an FCOI and whether the conflict has been managed, reduced, or eliminated.

9. Public Accessibility

- a. Ricoh will make a copy of this Policy available via a publicly available website.
- b. Before expending funds under an award, Ricoh will provide public accessibility (via a publicly accessible Web site or by written response to any requestor within five business days of a request) to information concerning any Significant Financial Interest disclosed that meets the following three criteria:
 1. The Significant Financial Interest was disclosed and is still held by the Senior/Key Personnel;
 2. Ricoh has determined that the Significant Financial Interest is related to the Research funded through an award; and
 3. Ricoh has determined that the Significant Financial Interest is a Financial Conflict of Interest.
- c. The information that Ricoh will make available will include the following (at a minimum):
 1. The Investigator's name;
 2. The Investigator's title and role with respect to the Research project;
 3. The name of the entity in which the Significant Financial Interest is held;
 4. The nature of the Significant Financial Interest; and
 5. The approximate dollar value of the Significant Financial Interest in the following ranges:
 - a. \$0—\$4,999;
 - b. \$5,000—\$9,999;
 - c. \$10,000—\$19,999;
 - d. Amounts between \$20,000—\$100,000 by increments of \$20,000;
 - e. Amounts above \$100,000 by increments of \$50,000); or
 - f. 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.
- d. If Ricoh uses a publicly accessible website to comply with the public disclosure requirements of the FCOI Regulations, then the information posted will be updated as required by the FCOI Regulations.
- e. If Ricoh responds to written requests for the purpose of public accessibility, then Ricoh will ascertain from the Investigator that the information provided is current as of the date of the correspondence and will note in its written response that the information is subject to updates as required by the FCOI Regulations.
- f. Information concerning the Significant Financial Interests of an individual will remain available as required by the FCOI Regulations.

10. Reporting Financial Conflicts of Interest

- a. Funds under an award may not be expended until (i) Ricoh has provided to the awarding body an FCOI Report compliant with the FCOI Regulations regarding any Investigator's Significant Financial Interest found to be conflicting, and (ii) the Investigator has agreed to and implemented the corresponding management plan. Ricoh may not incur expenditures until it has received notification to do so from the awarding body.
- b. While an award is ongoing, Ricoh will provide to the awarding body an annual FCOI Report as required by the FCOI Regulations.
- c. For any Significant Financial Interest that is identified as conflicting after an initial FCOI Report during an ongoing funded Research project, Ricoh will provide to the awarding body an FCOI Report regarding the Financial Conflict of Interest and, if applicable, implement a management plan to address the Significant Financial Interest.

11. Clinical Research

If the awarding body determines that one of its funded clinical Research projects 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 an FCOI that was not managed or reported by Ricoh, then the Investigator involved must disclose the Financial Conflict of Interest in each public presentation of the results of the Research and to request an addendum to previously published presentations.

12. Record Retention

Investigators and Investigator Managers shall retain relevant records under this Policy for the period required under the FCOI Regulations.