

Rigaku Americas Corporation
Financial Conflict of Interest Policy
Revision 1
March 15, 2021

1. Introduction

- 1.1. This financial conflict of interest policy is intended to be consistent with federal and state laws and regulations. Where there is a discrepancy, the applicable federal or state law, or regulation will take precedence.

2. Scope

- 2.1. This policy applies to Rigaku Americas Corporation (hereinafter referred to as Rigaku) which meets the definition of an Institution having responsibilities under 42 CFR 50 Subpart F. This policy also applies to Investigators of Subrecipients, whereas such Investigators have responsibilities under 42 CFR 50 Subpart F.

3. Definitions

- 3.1. **Disclosure of significant Financial Interests:** Disclosure of an Investigator's significant financial interests to Rigaku.
- 3.2. **Financial Interest:** Anything of monetary value, whether or not the value is readily ascertainable.
- 3.3. **Financial Conflict of Interest ("FCOI"):** A significant financial interest that could directly and significantly affect the design, conduct or reporting of PHS funded research.
- 3.4. **FCOI Review Committee ("FCOIRC"):** The Rigaku committee whose remit is to protect the integrity of externally-funded research, by identifying and resolving financial conflicts of interest in research. The DRC conducts its duties in a manner intended to promote, not hinder, research relationships.
- 3.5. **Institution:** Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.
- 3.6. **Investigator:** Any person who is independently responsible for making decisions regarding PHS funded research. This would include both the Principal Investigator on a research study, and anyone else, regardless of title, who is responsible for the design, conduct, or reporting (i.e. key personnel) of research funded by the PHS. For any one individual, the policy includes a financial interest of any immediate family member (spouse or spousal equivalent, and dependent children) as if any financial interest of that family member were one of the individual. Investigators include both those currently working on PHS projects, and those who may in the future become associated with PHS projects.

- 3.7. Manage:** Taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- 3.8. PD/PI:** Project director or principal investigator of an NIH-funded research project. The PD/PI is included in the definitions of senior/key personnel and Investigator for the research project
- 3.9. PHS:** Public Health Service of the U.S. Department of Health and Human Services, including the National Institutes of Health (NIH).
- 3.10. Research:** A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, book chapter, or patent) and product development (e.g., a diagnostic test or instrument).
- 3.11. Senior/Key Personnel:** The PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to NIH by Rigaku.
- 3.12. Significant Financial Interest (“SFI”):** Anything of monetary value or potential monetary value that reasonably appears to be related to the individual's duties and responsibilities, including, but not limited to:
- 3.12.1. Payment for service (e.g., a consulting fee, reimbursed travel, lecture payment, or honorarium), except as otherwise excluded by this policy
 - 3.12.2. A gift (e.g., money, hospitality, or a physical item);
 - 3.12.3. An equity interest (e.g., stock, stock option, security, or other ownership interest);
 - 3.12.4. An intellectual property right (e.g., a patent, copyright, or royalty from such right); and
 - 3.12.5. Other interests as determined by the company. For example, a financial interest may only have potential to be of value, like an option in a non-publicly traded company. Because this potential value may be an economic incentive, a situation like this is considered a financial interest.
 - 3.12.6. The term SFI does not include:
 - 3.12.6.1. Ownership of a share in a mutual fund, index fund or exchange traded fund; Salary or other remuneration from Rigaku or an accredited institution of higher education;
 - 3.12.6.2. Salary or other remuneration a federal, state, or local government entity.
- 3.13. Subrecipient:** One of the entities listed in a grant that receives a subaward from a pass-through entity (Rigaku) to carry out part of an NIH grant.

4. Policy and Process

4.1. Training Requirements

- 4.1.1. As part of the training requirements, Rigaku shall provide a copy of this policy to any Investigator involved in PHS-funded research.
- 4.1.2. Each Investigator shall all be required to complete the FIOC Tutorial at [FINANCIAL CONFLICT OF INTEREST - NEWEST \(nih.gov\)](https://www.nih.gov/financial-conflict-of-interest) and present a certificate of completion.
- 4.1.3. This training shall occur
 - 4.1.3.1. No later than the time of application for PHS-funded research
 - 4.1.3.2. Every four (4) years
 - 4.1.3.3. Immediately
 - 4.1.3.3.1. When an Investigator is new to Rigaku
 - 4.1.3.3.2. When this Policy is revised
 - 4.1.3.3.3. When an Investigator is not in compliance with the Policy or management plan

4.2. Disclosure, Review and Monitoring Requirements

- 4.2.1. It is the policy of Rigaku that an Investigator must disclose any SFI of the Investigator, spouse and dependent children, to Rigaku
 - 4.2.1.1. No later than the time of application for PHS-funded research
 - 4.2.1.2. Annually during the period of the award
 - 4.2.1.3. Within 30 days of discovering or acquiring a new SFI

4.3. Establishment of Financial Conflict of Interest Review Committee

- 4.3.1. A financial conflict of interest review committee will be appointed by the President of Rigaku company and the committee will report to the President.
- 4.3.2. The FCOIRC is the body responsible to solicit and review disclosures of SFIs of the Investigator, Investigator's spouse and Investigator's dependent children related to the Investigators responsibilities to Rigaku.

4.4. Procedures for Evaluation of Potential Financial Conflicts of Interest

- 4.4.1. The FCOIRC will determine who is classified as an Investigator. The committee will review all disclosure statements, and determine if a significant FCOI exists. If the committee determines that a significant FCOI exists, the committee will develop a management plan for the FCOI, meet with the Investigator to review the plan and obtain the Investigator's acceptance of the plan. Annually, the FCOI committee will present the status of disclosures and management plans to the President of Rigaku Americas Corporation. The FCOI committee will also be responsible for all required reporting of significant FCOI to NIH as required by the regulation.

4.5. Management of Financial Conflicts of Interest

4.5.1. The FCOIRC committee will oversee the implementation of the management plan, which may include the elimination of the financial conflict of interest, approval of a management plan, or adoption of an alternative course of action.

5. Reporting Requirements to NIH

5.1. The FCOIRC shall send initial, annual and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for Rigaku and its Subrecipients, as required by the regulation.

5.1.1. Prior to the expenditure of funds

5.1.2. Within 60 days of addition of a new Investigator to the NIH funded project

5.1.3. Within 60 days of a new or newly identified FCOI for an Investigator

5.1.4. At least annually at the time of submission of the annual progress report, multi-year progress report, at the time of extension to provide the status of the FCOI and any changes to the management plan until the project is complete.

5.2. The FCOIRC shall promptly notify NIH if bias is found in the design, execution or reporting of NIH-funded research. This shall include the requirement to submit a Mitigation Report in accordance with 42 CFR 50 Subpart F.

5.3. The FCOIRC shall promptly notify NIH if an Investigator fails to comply with Rigaku's FCOI policy or an FCOI management plan appears to have biased the design, execution or reporting of NIH-funded research.

6. Maintenance of Records

6.1. The FCOIRC shall maintain all FCOI-related records for at least three (3) years from the date the last expenditure report is submitted to NIH.

7. Enforcement Mechanisms and Remedies for Noncompliance

7.1. The FCOIRC shall enforce Investigator compliance with this FCOI policy and management plans through administrative action up to and including termination.

7.2. The FCOIRC shall complete and document retrospective reviews, consistent with 42 CFR 50 Subpart F, within 120 days of the determination by Rigaku of noncompliance for SFIs not previously disclosed or disclosed in a timely manner, or whenever an FCOI is not properly identified or managed in a timely manner.

7.3. In the event the Department of Health and Human Services determines that an NIH-funded research 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 an FCOI that was not managed or reported by the

Institution as required by the regulation, the Institution shall require the Investigator involved to disclose the FCOI in each publication of the results of the research and request an addendum to previously published presentations.

8. Subrecipient Requirements

8.1. Subrecipients will be required to comply with the FCOI policy of the subrecipient.

8.1.1. If applicable, the FCOIRC shall obtain certification that the subrecipient complies with 42 CFR 50 Subpart F.

8.1.2. If applicable, the FCOIRC shall include in the written subrecipient agreement the requirement for the subrecipient to report identified FCOIs for its Investigators in a timely manner so that Rigaku can report FCOIs to NIH as required by 42 CFR 50 Subpart F.

9. Public Accessibility Requirements

9.1. Rigaku shall post this policy on its website: www.Rigaku.com

9.2. Rigaku shall make public information concerning identified FCOIs held by by senior/key personnel (as defined by 42 CFR 50 Subpart F.) including:

9.2.1. The elements required by 42 CFR 50 Subpart F.

9.2.1.1. Project number

9.2.1.2. Project title

9.2.1.3. PD/PI

9.2.1.4. Name of the Investigator with the FCOI

9.2.1.5. Name of the entity with which the Investigator has a FCOI

9.2.1.6. Reason(s) for the retrospective review

9.2.1.7. Detailed methodology used for the retrospective review

9.2.1.8. Findings of the review

9.2.1.9. Conclusions of the review

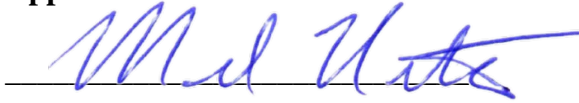
9.2.2. Rigaku shall post the information in section 10.2.1 on www.Rigaku.com within 5 days of a written request

9.2.3. The information concerning identified FCOIs shall be updated annually.

9.2.4. The information concerning identified FCOIs shall be updated within 60 days of a newly identified FCOI

9.2.5. The information concerning identified FCOIs shall remain available for three (3) years from the recent update of the FCOI information.

10. Approvals



Mel Kitagawa

Senior Vice President

March 16, 2021

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Review and Revision History:				
Version Number	Review Date	Reviewer	Reason for Review and/or Revision	Training
1	2021-03-15	J. Ferrara	Document creation	
2	2021-03-xx	M. Kitagawa	Update to comply with new company standard.	Yes

