



## **AMERICAN COLLEGE OF RADIOLOGY FINANCIAL CONFLICT OF INTEREST IN RESEARCH POLICY**

Chancellors, officers, committee or commission members, staff, volunteers, investigators and all others representing or acting on behalf of the American College of Radiology (ACR) should avoid conflicts of interest or the appearance of conflicts of interest. All decisions and actions considered or made by such individuals should be based solely on the best interests of the ACR and in accordance with applicable federal, state, and local laws and regulations. Personal considerations should not be a factor in any action or decision made on behalf of the ACR. The confidence that members of the profession and the public have depends on the integrity of those who represent the ACR.

### **Conflict of Financial Interest in Research**

As a recipient of National Institutes of Health (NIH) grant funds, the American College of Radiology is subject to the NIH requirement for grantees and investigators to comply with the requirements of 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research." In the handling of all such grant funds the ACR will take steps to ensure that the Investigator and any other persons responsible for the design, conduct or reporting of all research funded by Public Health Service (PHS), or proposed for such funding will not be biased by any conflicting "significant financial interest." For purposes of this policy and in compliance with Section 50.603 of the regulation "Investigator" means Principal Investigator and/or any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by the Public Health Service (PHS) of the US Department of Health and Human Services (HHS) and includes the individual's spouse and dependent children. This provision applies to all persons representing or acting on behalf of the ACR (including individuals engaged in RTOG, ACRIN or other specific ACR research activities).

### **What Constitutes a Financial Conflict of Interest (FCOI)?**

A "significant financial interest" (SFI) exists when one or more of the following interests are met by the Investigator including his/her spouse and dependent children, when aggregated exceeds \$5,000.

Regarding any publicly or non-publicly traded entity, in the twelve months preceding the disclosure; remuneration includes salary and any payments for services not otherwise identified as salary, including,

- Consulting fees, honoraria, paid authorship and other payments for service
- Equity interest including stock, stock options or other ownership interests or
- Intellectual property rights and interests

Investigators must also disclose the occurrence of any reimbursed or sponsored travel (i.e. that which is paid on behalf of the investigator) including the purpose of the trip, sponsor/organizer, destination, and duration, when related to their institutional responsibilities.

Excluded from disclosure is income or travel related to seminars, lectures, or teaching engagements sponsored by and service on advisory 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.

42 CFR Section 50.603 provides further information regarding what does and does not constitute a significant financial interest.

### **Disclosure of Significant Financial Interest**

Disclosure of a significant financial interest is required when the Investigator makes application to participate in the research supported by NIH funds and/or prior to expenditure of funds. A form will be provided by the ACR to the Investigator for this purpose. The form will be completed by the Investigator and returned to the ACR. This disclosure requirement is considered an “on-going” obligation of the Investigator, requiring submission of the appropriate documentation, within 30 days of discovering or acquiring a new significant financial interest, should his/her financial interests change during the course of the research. At a minimum, the Investigator will be required to complete and submit to the ACR a new conflict of interest form annually or a new assurance form from the institution.

All financial disclosure forms will be reviewed by the COI Coordinator; if a potential significant financial interest is disclosed, the coordinator will send the disclosure to the appropriate person(s). The disclosure will be reviewed by the administrator of the research activity (i.e., ACRIN, RTOG) involved with guidance from ACR legal counsel. Any identified FCOI will be reviewed with the affected Investigator and reported to NIH within 60 days of its discovery by the ACR and actions to manage, reduce or eliminate the FCOI will be taken by the administrator of the research activity involved with advice from legal counsel and included in the report to NIH. Management of an identified FCOI will include the development and implementation of a management plan and, if necessary, a retrospective review and mitigation report, submitted to NIH. All financial disclosure forms and any actions taken by the ACR to resolve an FCOI will be recorded and kept on file in accordance with Section 50.604(e) of the regulation.

Institutions through which investigators provide services to the ACR shall provide ACR with “certification” that the Institution is compliant with the financial conflict of interest requirements of 42 CFR 50, Part F. A form will be provided by ACR as an addendum to the Institution’s annual ACR agreement. Institutions will provide signature as testament to institutions compliance with 42 CFR 50, Part F and that as per this regulation the institution has an up-to-date, written and enforced policy on FCOI in place and that the investigator(s) have completed appropriate training related to FCOI. Institutions must also notify ACR of any identified FCOI and if an Institution has identified an Investigator as failing to comply with the Institution’s conflict of interest policy and such failure has biased the design, conduct or reporting of PHS-funded research the Institution must promptly notify ACR of any corrective action taken or to be taken.

Such notification to ACR is necessary so that ACR can consider the situation, comply with its reporting obligations to NIH, take appropriate action or refer the matter back to the Institution for further action, including instructions to the Institution on how to maintain appropriate objectivity for the funded project.

Pursuant to this regulation, as of September 26, 2011, Investigator Training, related to this regulation, is required for all investigators participating in PHS funded research. Investigators will provide the date training was completed. If an investigator has not completed training at the time of submission of their FCOI response form, ACR will make available appropriate training. Investigators are not permitted to commence research until training is completed. Proof of training may be requested.

### **Financial Conflict of Interest Disclosure Forms**

In addition to the above guidance, formal Financial Conflict of Interest disclosure forms will be required from the following groups of individuals on an annual and ongoing basis or at the commencement of a research activity:

- Group leadership (i.e., ACRIN, RTOG)
- Scientific and support committee chairs
- Clinical trial investigators
- Data and Safety Monitoring Committee members
- Research Consultants
- Speakers at ACRIN, RTOG or other ACR research meetings
- ACR Institutional Review Board (IRB) Members
- ACR Personnel

The form will include a brief description of the ACR FCOI policy, a request to report any significant financial interest and the date of completion of FCOI training.

A Financial Conflict of Interest form must be submitted:

- Prior to application for PHS-funded research
- Prior to initiation of a project
- Addition of a new investigator
- Prior to expenditure of funds
- Within 30 days of discovering or acquiring a SFI

### **Management and Enforcement**

Management and enforcement of this policy is the responsibility of the administrator of the research activity (i.e., ACRIN, RTOG) affected, with involvement from the respective Clinical Chair and ACR Executive Director. In the case of reported FCOI such actions to manage, reduce or eliminate the conflict of interest may include, but are not limited to, public disclosure of the FCOI, disclosure of the FCOI directly to participants, appointment of an independent monitor, modification of the research plan, change of personnel or personnel's responsibilities, or disqualification of personnel from participation in the research, reduction or elimination of the FCOI, or severance of relationships that create financial conflicts.

Any significant conflict of financial interest not reported but discovered during the course of a research activity will be immediately investigated by the administrator of the research activity involved, with assistance from ACR legal counsel. Reporting to NIH will be in accordance with the guidance described above. Depending upon the nature of the FCOI and the facts surrounding the failure of reporting in accordance with 42 CFR Part 50, Subpart F, corrective action to reduce, or eliminate the conflict of interest will at a minimum include consideration of those actions described above. In addition, ACR may take more punitive action such as elimination of the Investigator and/or the Institution involved from further participation in ACR research activities.

ACR will make certain information available concerning identified FCOI held by investigators via a publicly accessible Web site and update such information in accordance with Section 50.605 of the regulation.

### **Notice**

All institutions and individuals providing or engaged in research activities for the ACR will be provided with a copy of this policy.



**FINANCIAL CONFLICT OF INTEREST RESPONSE FORM**

In accordance with ACR policy, you serve in a role which requires you to complete this response form. Do you, your spouse or dependent children have **either** a relationship or financial interest, when aggregated, is in excess of \$5,000 with any business, organization or other activity that may conflict or appear to conflict with your duties, responsibilities or exercise of independent judgment in any transaction or matter involving ACR?

YES  NO

If you answered “YES” please describe the nature of the relationship or financial interest, investment or **personal** compensation you have received in the preceding 12 months, **on the Confidential Financial Disclosure Form<sup>1</sup> (included with this form).**

A conflict does not necessarily imply that an individual is ineligible to serve in the assigned role. A conflict may, however, limit participation on specific activities. Financial conflicts of interest over \$5,000 must be reported to the NCI. During the course of your participation on ACR activities, any change in your status that could constitute a conflict or potential conflict must be reported, in writing, to ACR.

**FCOI Training:** Investigators are required to complete FCOI training related to Financial Conflict of Interest every four years. Please provide the most recent date that you completed FCOI training. Proof of training may be requested. If you have not completed training, ACR will provide an online training course for you to complete.

Date of FCOI Training: \_\_\_\_ / \_\_\_\_ / \_\_\_\_      \_\_\_\_\_  
Initials

**ACKNOWLEDGMENT**

I acknowledge that I have read and understand the above requirements for reporting any potential or actual financial conflicts of interest during my tenure with ACR.

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Please return to:**  
ACR Conflict of Interest Coordinator - COI@ acr.org

<sup>1</sup> Complete one form per company.



## Confidential Financial Disclosure

<b>Name:</b>	<b>Date:</b>
<b>Company / Organization Name:</b>	

**Instructions:** Describe the nature of the relationship or financial interest, investment or **personal** compensation you have received in the preceding 12 months by **completing this table.**

		\$0 - \$4,999	\$5,000 - \$9,999	\$10,000 - \$24,999	\$25,000 - \$49,999	>\$50,000
Serve on an Advisory Board (AB)	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Serve on a Board of Directors (BOD)	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Consulting (other than AB or BOD)	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Position in the company	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Product evaluation payments	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Publication agreement or royalties for books	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Fees/Honoraria for company sponsored lectures	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Stock ( <i>excluding diversified mutual funds</i> )	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Stock options	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Partnership, warrants or other ownership interest	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Intellectual property rights and interests	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Licensing agreement or royalties for inventions	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				
Other (describe below):	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/>				

Describe your financial interest, including your spouse and/or dependent children, with this company and how it may relate to your research:

Is the <b>aggregated</b> total financial relationship less than \$5,000?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Is the <b>aggregated</b> total financial relationship greater than \$25,000?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Is this financial interest potentially related to any of your research with ACR?	<input type="checkbox"/> No <input type="checkbox"/> Yes
<b>If yes please identify</b> _____	
Do you use, prescribe, or recommend to your patients any products from these companies?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Printed Name

Signature

Date