

As used herein, “Associated Parties” shall mean those Board members and officers, committee members, staff, volunteers, clinical investigators and all others representing or acting on behalf of the RTOG Foundation, Inc. (“RTOG”), and shall also include those with which or with whom RTOG has contracted for services. It is the stated policy of RTOG that all Associated Parties, including the employees, agents, officers and directors of such Associated Parties, avoid conflicts of interest or the appearance of conflicts of interest. All decisions and actions considered or made by Associated Parties shall be based solely on the best interests of RTOG 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 or in contracting with RTOG. The confidence that members of the profession and the public have depends on the integrity of those who represent RTOG and those with whom RTOG conducts business.

Conflict of Financial Interest in Research

As a recipient of National Institutes of Health (“NIH”) grant funds and grant funding from industry collaborators, RTOG 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,” with respect to the former, and with 21 CFR Part 54, “Financial Disclosure By Clinical Investigators,” with respect to the latter. In the handling of all such grant funds, RTOG 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 Federal Regulations, “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) as well as research funded by industry collaborators and includes the individual’s spouse and dependent children. This provision applies to all Associated Parties.

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 (12) 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 and 21 CFR Section 54.4 each provide 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 or industry collaborator funds and/or prior to expenditure of funds. A form will be provided by RTOG to the Investigator for this purpose. The form will be completed by the Investigator and returned to RTOG. This disclosure requirement is considered an “on-going” obligation of the Investigator, requiring submission of the appropriate documentation, within thirty (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 RTOG 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 RTOG administrator with guidance from RTOG legal counsel. Any identified FCOI will be reviewed with the affected Investigator and if applicable reported to NIH within sixty (60) days of its discovery by RTOG 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 if applicable. Management of an identified FCOI will include the development and implementation of a management plan and, if necessary, a retrospective review and mitigation report, and if applicable submitted to NIH. All financial disclosure forms and any actions taken by RTOG to resolve an FCOI will be recorded and kept on file in accordance with 42 CFR Section 50.604(e) and 21 CFR Section 54.6 of the Federal Regulations.

Institutions through which investigators provide services to RTOG shall provide RTOG with “certification” that the Institution is compliant with the financial conflict of interest requirements of 42 CFR 50, Part F and 21 CFR 54. A form will be provided by RTOG to assist in reporting FCOI. Institutions will provide signature as testament to institution’s compliance with 42 CFR 50, Part F and 21 CFR 54 and that as per these Federal Regulations, 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 RTOG 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 or industry

collaborator-funded research, the Institution must promptly notify RTOG of any corrective action taken or to be taken.

Such notification to RTOG is necessary so that RTOG can consider the situation, comply with its reporting obligations to NIH and or the industry collaborator, 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.

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, RTOG 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:

- RTOG leadership
- Scientific and support committee chairs
- Clinical trial investigators
- RTOG Data Monitoring Committee members
- Research Consultants
- Speakers at RTOG-sponsored research meetings
- RTOG Personnel

The form will include a brief description of the RTOG 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 thirty (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 affected. 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 RTOG 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 and 21 CFR 54, corrective action to reduce, or eliminate the conflict of interest will at a minimum include consideration of those actions described above. In addition, RTOG may take more punitive action such as elimination of the Investigator and/or the Institution involved from further participation in RTOG research activities.

RTOG will make certain information available concerning identified FCOI held by NIH-funded investigators via a publicly accessible Web site and update such information in accordance with Section 50.605 of the Federal Regulation.

Notice

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